行政院及所屬機關出國報告
（出國類別：其他）

赴科威特擔任「良好市場監督作法」課程講師

服務機關：經濟部標準檢驗局
姓名職稱：鍾繼磊科員
派赴國家：科威特
出國期間：106 年 9 月 30 日至 106 年 10 月 6 日
報告日期：106 年 12 月 15 日

摘　要

海灣國家合作理事會標準組織（GCC Standardization Organization,簡稱 GSO）針對海灣國家合作理事會（Gulf Cooperation Council, 簡稱 GCC）之成員國於 106 年 10 月 2 日至 4 日在科威特舉辦「良好市場監督作法（Good Market Surveillance Practices）」訓練課程。

該訓練課程由經濟部標準檢驗局派員講授該局之「商品後市場監督管理機制」，另有其他領域專家講授品質管理與市場監督概念。本次參與該研討會議之心得及建議如下：

一、 海灣國家目前尚未建立商品後市場監督機制，需仰賴歐美國家協助，本國可藉由持續派員參與，增加合作深度。

二、 未來可評估採行完整的商品風險評估機制，強化整體市場商品安全。

關鍵字：GSO、市場監督作法

目　次

壹、出國目的

海灣國家合作理事會（Gulf Cooperation Council, 簡稱 GCC）係於 1981 年 5 月 25 日在阿拉伯聯合大公國阿布達比成立，其成員國分別為科威特、卡達、阿拉伯聯合大公國(UAE)、阿曼、沙烏地阿拉伯、巴林等六個中東國家，前述六國政經體制相似，王室聯繫緊密，在政治、經濟、外交、國防等方面有著共同的利益，是中東地區一個十分重要的政經合作組織。而 GCC 為了達成區域內 6 國間之協調、一致性與密切合作，乃依據海灣國家合作理事會之決議，建立一海灣國家合作理事會之標準組織（GCC Standardization Organization,簡稱 GSO）

海灣國家合作理事會之標準組織（GSO）根據組織內成員之要求，每年均會安排不同之培訓計畫以達成(1)成員國內國家標準機構人員之技術能力開發、(2)藉由區域間的一致性觀念，消除成員國間技術障礙以擴大貿易往來、(3)消費者保護等[1]。

為協助國內產業拓銷海外市場、增加我國於國際場域能見度、及掌握國際標準與技術性法規之最新趨勢，經濟部標準檢驗局（以下簡稱標檢局）由局長率團於 105 年 9 月 25 日赴沙烏地阿拉伯王國首都利雅德與 GSO 簽署「技術合作瞭解備忘錄」，該備忘錄合作範圍涉及標準、度量衡、符合性評鑑、認證及品質等領域，合作項目包括資訊交換、專家互訪、人員訓練及舉辦研討會等。

而為進一步落實該備忘錄內容與確認標檢局與 GSO 未來合作方向，另與其簽署「技術合作瞭解備忘錄執行路徑圖」，除將備忘錄執行時程分為 4 季外，亦將未來可執行之活動臚列，本次出國計畫即依據 GSO 年度訓練計畫（如圖 1），由標檢局派講師出席授課。

GSO 年度訓練計畫中包含「良好市場監督作法（Good Market Surveillance Practices）」主題，基於我國後市場管理機制完備，藉由派員講授我國商品檢驗市場督作法，除加強海灣國家對我國商品管理制度之認識，提高對我國出口商品品質及安全之信心外，及瞭解 GSO 市場監督機制，藉此加強合作深度。

[1] 詳參 GSO 網站
(https://www.gso.org.sa/gso-website/gso-website/activities/training/training-program-goals)

هيئة التقييس
لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization

الخطة التدريبية لأجهزة التقييس الوطنية بالدول الأعضاء ٢٠١٧م

GSO Training courses Plan 2017

م	البرنـــــــــامج	الأيام	التاريخ	المكان
١	التقييس ودوره في دعم المنشئات الصغيرة والمتوسطة Standardization and its role in supporting SMEs	٣	٢٠١٧/٠١/٢٥-٢٣	السعودية
٢	إعداد وتطوير التشريعات واللوائح الفنية Technical Regulations Development	٣	٢٠١٧/٠٢/٨ -٦	السعودية
٣	السيارات الكهربائية - المميزات والبنية التحتية اللازمة لها Electric Vehicles: Advantages & Required Infrastructure	٣	٢٠١٧/٠٢/١٥-١٣	البحرين
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١٠	ورشة عمل: تفعيل إتفاقيات التعاون وأساليب استفادة الدول الأعضاء منها Enhancing cooperation and MoUs workshop	٣	٢٠١٧/٠٧ /٢٦-٢٤	قطر
١١	الممارسات الجيدة لمسح الأسواق Good Market Surveillance Practices	٣	٢٠١٧/١٠/٤-٣	الكويت
١٢	البنية التحتية لتكنولوجيا المعلومات Information Technology Infrastructure Library (ITIL)	٣	٢٠١٧/١٠/١٨-١٦	السعودية
١٣	المتطلبات الخليجية لتعيين جهات تقويم المطابقة تطبيق عملي على الأجهزة الكهربائية منخفضة الجهد ولعب الأطفال (مستوى متقدم) GCC Notification Requirements for CABs	٣	٢٠١٧/١٠/٠١-٣٠	الإمارات
١٤	الاشتراطات الكهربائية في كود البناء الخليجي in GBC Electricity Requirements	٣	٢٠١٧/١١/٨-٦	الكويت
١٥	تدريب مدربين (متقدم) Train of Trainers	٥	٢٠١٧/١١/١٦-١٢	قطر

مركز التقييس الخليجي للتدريب
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التسجيل في البرامج التدريبية يمكنكم زيارة الموقع الإلكتروني للهيئة
www.gso.org.sa/tr

圖 1：GSO 年度訓練計畫(2017)

貳、會議議程

良好市場監督作法研討會

一、時間：2017 年 10 月 2 日~10 月 4 日

二、地點：科威特

三、研討會議程：

分別有 3 位講師以阿拉伯語或英語授課（含標準檢驗局），授課議程與講師安排如下表，會後並授予結業證書。

日期	議題
10 月 2 日	1. 市場監督作法簡介-1（Introduction to market surveillance good practices – part 1)(阿拉伯語授課） 講師：Abdesselam Benyaich[2], GSO 2. 品質管理簡介(Introduction to the Quality Management System)（英語授課） 講師：Ivan Hendirkx
10 月 3 日	**1. 台灣消費性商品之市場監督機制（The Market Surveillance Mechanism of Consumer Products in Taiwan）（英語授課）** **講師：鍾繼磊,標準檢驗局** 2. 品質管理應用於市場監督（Quality Management for Market Surveillance）（英語授課） 講師：Ivan Hendirkx 3. 市場監督作法簡介-2（Introduction to market surveillance good practices – part 2)(阿拉伯語授課） 講師：Abdesselam Benyaich, GSO
10 月 4 日	1. 品質管理應用於市場監督（Quality Management for Market Surveillance） （英語授課）

[2] Abdesselam Benyaich 是 GSO 技術規範部門的負責人（Head of Technical Regulations）

	講師：Ivan Hendirkx 2. 品質管理之支援程序（The Supporting Processes）（英語授課） 講師：Ivan Hendirkx 3. 總結及授予結業證書（Review of the workshop and Hand-out of certificate）

參、參與良好市場監督作法研討會之重要議題摘述

一、市場監督作法簡介（講師：**Abdesselam Benyaich**）

（一）GSO 旨在協調並實現海灣國家合作理事會"經濟協定"的各項目標，藉由統一各種標準化活動，並與各成員國的標準化機構進行合作與協調，努力發展製造與服務業，促進海灣國家內部貿易，保護消費者、環境和公眾健康，並鼓勵成員國之工業和農業生產以強化 GCC 之經濟，保持成員國的成就並儘可能減少海關聯盟所設想的技術性貿易障礙[3]。因此，為達成海灣國家合作理事會之目標，藉由成員國之合作與協調，並達到保護消費者與公眾健康之目標，市場監督作法將是未來重要的一環。

（二）本節課程主要講授市場監督之重要性與期許各國針對市場監督一致性作法之建立。因目前 GSO 僅將玩具及低電壓產品列檢，雖然多數民眾了解商品（例如玩具、低電壓產品）安全的重要性，而 GSO 各會員國尚未建立完整的市場監督機制，現在正要積極建立各會員國的市場監督制度，包括各國標準、法規與檢測能量的一致性與連動，透過各類研討會的方式，訓練會員國主要負責市場監督業務之承辦人員相關概念，建立各會員國內部之系統建置，以達成海灣國家組織間主動的市場監督機制。

二、品質管理簡介與應用於市場監督（講師：**Ivan Hendirkx**）

（一）何謂品質管理：品質管理是用來協助組織規劃、確保、控制及改善產品/服務的過程；並幫助組織致力於持續提供符合顧客期望及法令規範之產品及服務。

（二）為何要應用品質管理於市場監督？

品質管理要求書面程序，而書面程序是為了確保：（1）對企業及消費者的法律確定性、（2）一致性的決策、（3）增加管理透明度、（4）持續改進、（5）更容易培訓新進員工；也能符合 ISO/IEC 17020:2012 的一般規定。

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[3] 詳參 GSO 網站(https://www.gso.org.sa/gso-website/gso-website/about-gso/about/bylaw)

而品質政策的目標在於：

1. 保護各 GSO 成員國內之消費者、
2. 確保市面上販售且使用的皆為安全且符合規定之商品、
3. 確保企業以合法的方式進行生產銷售，且各會員國間皆以協調一致的方式進行、
4. 透過檢查機制，確保有效保護 GSO 的國家利益
5. 建立有效且有效率的市場監督系統
6. 確保公平的經濟環境
7. 與其他國家相關機構進行跨國合作

為了達成前述的目標，會採行以下行動：

1. 將國家的產品安全及市場監督法令的目標轉化為實際的關鍵績效指標(KPIs)；
2. **依據風險評估來強化市場監督作法**；
3. 對所有關鍵信息做出相對應的措施；
4. 提升一般大眾的消費意識；
5. 讓 GSO 會員國內都具有能力且訓練有素的工作人員履行職責；
6. 分配設備、資料庫及檢測能力等資源；
7. 深化與各政府組織、司法機關等主管機關的合作；
8. 配合各國家的經濟運作等措施。

（三）市場監督之準備（依據 Quality Manual, chapter 9）

歐盟的市場監督事前準備有以下 8 個程序：

1. 系統級取樣（System level sampling）：

本項程序目的在於（1）決定所需的數量來評估合格率；（2）獲得市售商品的未知參數的估計數。而透過系統級的取樣方式是為了在有限的成本來確認參數的正確性，以用於風險評估。

2. 非食品商品的市場監督活動計畫（Planning of market surveillance activities for non-food products）：

市場監督活動計畫的目標希望能（1）確保商品的利害關係人皆能適當的涵括在計畫內、（2）確保已規劃的監督計畫能在預算內，且與

市場監督人員數量工作量相符、（3）辨別預算調整及人員配置的需求。

3. 檢測計畫（Test plan）：

   歐盟針對檢測計畫的要件為：（1）確認適用的技術規範、（2）確認商品應符合的基本要求、（3）確認適用的統一標準、（4）決定產品測試的範疇（標準中全項檢測或是部分測試）等。

4. 非食品商品的反應性市場監督（Reactive market surveillance for non-food products）：

   反應性的市場監督有 4 個步驟：

   （1）收到事故通報；

   （2）將事故通報登記並初步蒐集資訊；

   （3）評估事故案件的等級分類：急迫、一般、或較不重要；

   （4）依據前點分類處理案件。

5. 標準的處理（Handling of standards）：為了確保有效的標準能應用在市場監督，必須要先確認相關計畫所適用的標準為何，且須持續關注技術發展並發布新的標準，並通知相關檢查人員最新適用的標準。

6. 法律訊息管理（Legislative information management），針對相關文件的收集、儲存、分析及維護的規定。

7. 市場監督專案執行（Running a market surveillance project），此程序強調市場監督專案的執行過程，包括檢查、取樣、測試商品、選擇指定(簽約)的實驗室、風險評估作法、強制作為、及專案報告等。

8. 市場監督個案執行（Running a market surveillance case），針對專案中不同個案的處理細節。

以下將就歐盟執行市場監督個案時的實際運作方式進行研討。

三、 市場監督個案之案例研討（講師：Ivan Hendirkx）

本次研討會提供以下案例：小鴨造型之拖拉玩具（如圖 2，EMARS Book

案例[4]）作為歐盟市場監督之風險評估作法之個案分析。

圖 2：具有可拆卸小物件的玩具

（一）預先的符合性測試（Examination and indicative or pre-compliance test）

1. 定義商品（Identify product）-此案例為玩具小鴨有輪子及拖拉繩
2. 商品取樣（Sample product）-
   (1) 當檢查人員懷疑商品可能會不符合或有潛在風險時，可至製造商、進口商、經銷商、賣場等各類企業經營場所進行取樣。
   (2) 一般取樣2件(1件送實驗室，1件備樣以防測試結果被業者挑戰)；如測試計畫規定要較多樣品，則依計畫規定取樣。
3. 檢視商品的技術文件（Examine technical documentation）-檢視業者提供的技術文件是否清楚定義商品，並且已簽署符合性聲明。
4. 商品預先測試（Indicative or pre-compliance test of the toy）-依據相關作業規定（例如本案例的玩具係依據 EN 71-1[5]執行測試）以最簡單之測試器具進行基本之測試(包括商品標示、警語與使用說明、小物件、銳邊銳角、繩帶等)，能花費最少的成本，而先無須送至指定實驗室

[4] 節錄自 EMARS Book Annex C.5, p.105.，詳附錄 3

[5] EN 71-1 為歐盟的玩具安全標準(Safety of toys - Part 1: Mechanical and physical properties)

進行完整測試，用以發現商品潛在的風險。

5. 測試結果回報（Reporting an indicative or pre-compliance test）-回報商品的測試方式、地點、測試人員等

（二）風險評估（Risk Assessment）：依據 EU RAPEX Guidelines[6]及 EMARS book[7]，用以判定商品對使用者的風險，

1. 描述商品及其適用年齡（Describe the product and which consumer group）：

   在這個案例中，是小鴨造型的拖拉玩具，因為其顏色與功能（ie intend function），適用於 0-3 歲的小孩（Very young children, 0-36 months），年紀稍長的小孩可能會覺得無聊。

2. 產品風險判定（Product hazard）：

   (1) 選定產品風險類別：

   RAPEX 主要分有 10 種風險類別-「Size, shape and surface」、「Potential energy」、「Kinetic energy」、「Electrical energy」、「Extreme temperature」、「Radiation」、「Fire and explosion」、「Toxicity」、「Microbiological contamination」、「Product operating hazards」。

   在本案例中，是屬於「Size, shape and surface」的風險類型。

   (2) 選定產品風險狀況：選定風險類別後，再依據產品狀況選擇實際的風險情況。

   在本案例中，依據前述風險類別「Size, shape and surface」又可區分 9 種風險狀況「Product is obstacle」、「Product is impermeable to air」、「Product is or contains small part」、「Sharp corner or point」、「Sharp edge」、「Slippery surface」、「Rough surface」、「Gap or opening between elements」、「Possibility to bite off small part from product」。

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[6] RAPEX Risk Assessment Guidelines Application，詳附錄 2

[7] EMARS Book (http://www.prosafe.org/images/Documents/EMARS/EMARS_Book_of_Best_Practice.pdf)

在本案例中，是屬於商品有小物件（「Product is or contains small part」）的風險狀況，如圖 3。

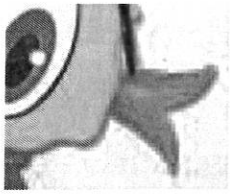

圖 3：小物件(鴨嘴造型)

3. 引起的傷害狀況（Injury scenario）：描述前述有小物件的風險狀況會導致的傷害—小孩會吞入小物件，小物件會卡在咽喉並阻礙氣管（Internal airway obstruction）。
4. 傷害的嚴重程度（Severity of injury）：RAPEX 系統有選單，可依據前述引起的傷害狀況，選擇嚴重程度（1~4，4 是最嚴重）。

   在本案例中，內部氣管阻礙（Internal airway obstruction）可能會發生的傷害嚴重程度是 3（缺氧但無永久性的傷害,Oxygen flow to brain blocked without permanent consequences）。
5. 發生傷害的機率（Probability）：在計算發生傷害的機率時，RAPEX 會建立傷害發生機率的各種狀況評估，本案例中有 4 種狀況(scenario)及不同的發生機率。

   (1) 小孩把玩具的鴨嘴剝離—預估發生機率 100%

   因為小孩好奇心旺盛、會咬玩具。另外會測試鴨嘴多容易會被分離。

   (2) 父母未注意—預估發生機率 50%

   依據專家的評估(An expert's best guess)，當小孩將小物件放入口中前，父母能提前發現的機率；此外，父母是否會注意不見的小物件(鴨嘴)。

   (3) 小孩將小物件(鴨嘴)放入口中—預估發生機率 100%

   依據專家(醫生)意見及相關研究文章，此種將東西放入口中是 0-1.5 歲小孩普遍的行為，所以預估發生機率是 100%。

   (4) 小物件(鴨嘴)進入孩童氣管，必須以手術才能移除—預估發生機率 0.1%

依據專家(醫生)意見及相關研究文章，因為小孩將小物件放入口中，不一定會進入氣管，而此種造型的小物件可能會讓小朋友吐出。所以發生要以手術移除的機率為 0.1%。

6. 整體風險計算（Combine and calculate risk）

根據系統計算後，本案例整體發生傷害的機率預估為 1/2,000 (p=0.0005)，大於 1/10,000，所以風險狀況屬於高風險(High risk)，節錄如下圖 4[8]

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
The child detaches the beak. The parents don't notice or don't react. The child puts the beak in his mouth. The small part goes into the child's airways and surgery is necessary.	Oxygen flows to brain blocked without permanent consequences	3	• Beak is detached 1/1 (p = 1) • Parents don't notice 1/2 (p = 0.5) • Child puts beak in mouth 1/1 (p = 1) • Beak gets in the child's airways 1/1,000 (p = 0.001)	1/2,000 (> 1/10,000) (p = 0.0005)	High risk

圖 4：小物件玩具的傷害狀況與風險計算

7. 有關風險評估的過程有幾點須注意的：

(1) 應避免主觀的判定（avoid subjective judgements）、

(2) 評估個案結果，並與實際發生事故機率進行比較；

(3) 建議以兩人或團體合作方式來判定；

(4) 由其他同事確認自己的風險評估是否有誤；

(5) 執行第一次的風險評估時建議以團體方式進行，並作為未來執行風險評估的基礎。

（三）與業者磋商（Consultation）

1. 測試結果評估（Evaluation of test results）
2. 磋商（Consultation）：提供相關測試結果予業者，並允許業者於 2 周內提供說明或意見，而業者在此階段可採行「**自願性措施**」來解決商品風險。

[8] 節錄自 The EMARS Books Annex C, table 12 ,p.105.，詳附錄 3

3. 提供測試結果予業者的郵件會包含以下內容：

(1) 產品鑑定、

(2) 執行各種鑑定的紀錄(包含取樣紀錄、鑑定測試紀錄、實驗室測試紀錄等

(3) 測試結果判定總結與結論

業者被要求在 2 周內提出說明或意見。

（四）決定處置措施（Deciding on Measures）

檢查人員必須判定何謂「妥適的處置（appropriate measure）」，根據以下標準：

(1) 處置措施需針對不安全商品、

(2) 處置措施必須迅速且有效、

(3) 要符合比例原則、

(4) 並有預防性措施

此外，歐盟有提供企業矯正措施指南（Corrective Action Guide[9]），可讓企業就商品召回、與商品矯正措施進行管理

四、 臺灣消費性商品市場監督機制

（一）授課重點摘要：

1. 商品主管機關：

目前臺灣經濟部負責一般消費性商品之監管，其中標準檢驗局會將部分商品列為強制檢驗商品，必須在輸入、運出廠場或進入市場前完成檢驗程序。標準檢驗局共設有 6 個分局，總人數 1,027 人，負責全國市場監督業務人數約 83 名。

另外，衛生福利部負責監管食品、藥品、化妝品及醫療器材；交通部負責監管汽機車；國家通訊傳播委員會負責行動電話與資通設備；環保署負責環境用藥與毒性化學物質等等。

2. 臺灣消費性商品之檢驗制度：

[9] EMARS II Consumer Product Safety in Europe , Corrective Action Guide (http://www.prosafe.org/images/Documents/EMARS/Corrective_Action_Guide_Final-published.pdf)

凡是商品無特定目的事業主管機關者均屬經濟部主管，由標準檢驗局依據消費者保護法執行商品之後市場監督。若經標準檢驗局指定公告列入強制檢驗之應施檢驗商品（目前超過 1200 種），標準檢驗局將依據商品檢驗法，執行「上市前檢驗」與「後市場監督」之檢驗制度。我國應施檢驗商品之檢驗制度為「前市場管理（上市前檢驗）」及「後市場監督（上市後管理）」雙軌併行制度；若為一般消費性商品，於上市前無須檢驗，由企業經營者確認商品具安全性即能自由流通於市場，商品上市後由標準檢驗局執行市場購樣檢測。

3. 臺灣商品市場監督管理機制之執行狀況：

臺灣執行商品後市場監督管理可分為 4 大面向（如下圖 2）：(1)不安全商品管理、(2)資訊掌握、(3)消費意識、(4)源頭控管等，各面向之執行情況分述如下：

(5) 不安全商品管理

為確保市售商品安全，標準檢驗局每年均會執行購樣檢測計畫、市場檢查計畫及網路市場管理。

①. 市場購樣檢測計畫

每年除針對危害風險較大及違規頻率較高之商品，並參酌檢討歷年檢驗結果，對於不合格率較高的商品及購樣地點每年持續辦理購樣檢測計畫，應施檢驗商品與非應施檢驗商品皆列入購樣計畫範圍。

105 年共執行購樣檢測 2,014 件（含應施檢驗商品 1,768 件及非應施檢驗商品 246 件）。經檢驗不符合者，將命製造商/進口商限期回收或改正，廢止其相關證書，並命銷售者下架。

②. 市場檢查計畫

依據商品違規風險程度訂定年度市場檢查計畫，另不定期針對流行商品辦理實體店面及網路通路之專案市場檢查計畫（如 106 年上半年執行指尖陀螺市場檢查計畫）。

目的在於確認應施檢驗商品標有「商品檢驗標識」及「中文標示」，每年檢查超過 5 萬筆商品資料（實體店面及網路通路），

若經查獲未經檢驗商品將通知銷售者下架停售。

③. 網路市場管理

為因應網路購物蓬勃發展之趨勢，及網路相關之檢舉案件逐年增加，故加強對於網路販售商品之市場管理。相關措施包括：

- 與網路平臺合作

  與主要網路購物（PChome 購物、Yahoo!購物）及拍賣平臺（露天拍賣、Yahoo!奇摩拍賣、蝦皮拍賣）建置標準局宣導資料路徑連結。另針對高風險或違規率較高之商品建置「賣家上架提醒」（露天拍賣）或商品檢驗標識選填欄位（蝦皮拍賣）

- 執行網路市場查核及追蹤調查

  每月針對國內 24 個主要網路購物及拍賣平臺進行查核至少 770 件，檢視網路銷售之商品是否揭示商品檢驗標識，若未揭示者，即通知網路平臺業者轉請賣家下架停售或移除該拍賣網頁，若賣家不自行移除拍賣網頁，則標準局將進行後續調查處分。

- 教育與宣導

  透過 Facebook 粉絲專頁「小安心」刊登商品安全資訊且即時回答網友意見，並不定期請網購平臺業者轉知賣家各類流行商品宣導資訊。

(6) 資訊掌握

針對有發生事故之高風險商品，標準檢驗局會要求製造/進口商執行事故通報，並辦理商品召回，以確保消費者權益；另持續蒐集國內外瑕疵商品訊息（RAPEX、CPSC 等），並透過義務監視員反映案件以提升市場監督成效。

(7) 消費意識

為強化消費者意識，標準檢驗局每年持續赴學校、賣場等地點辦理教育宣導活動；並與消費者文教基金會等非政府組織合作，適

時發布新聞稿，透過媒體力量來強化商品安全重要性，以提醒消費者注意。

(8) 源頭控管

自源頭把關，杜絕不安全商品於國內市場，針對已取得驗證登錄證書之廠商，執行邊境查核或工廠查核，以確保商品在進入試場前即符合檢驗規定。

亦定期分析後市場監督結果，調整不同市場監督作法，如：機動調整標準局市場查核之重點商品以因應市場變化、調整前市場檢驗方式或評估修訂國家標準以符合現況。

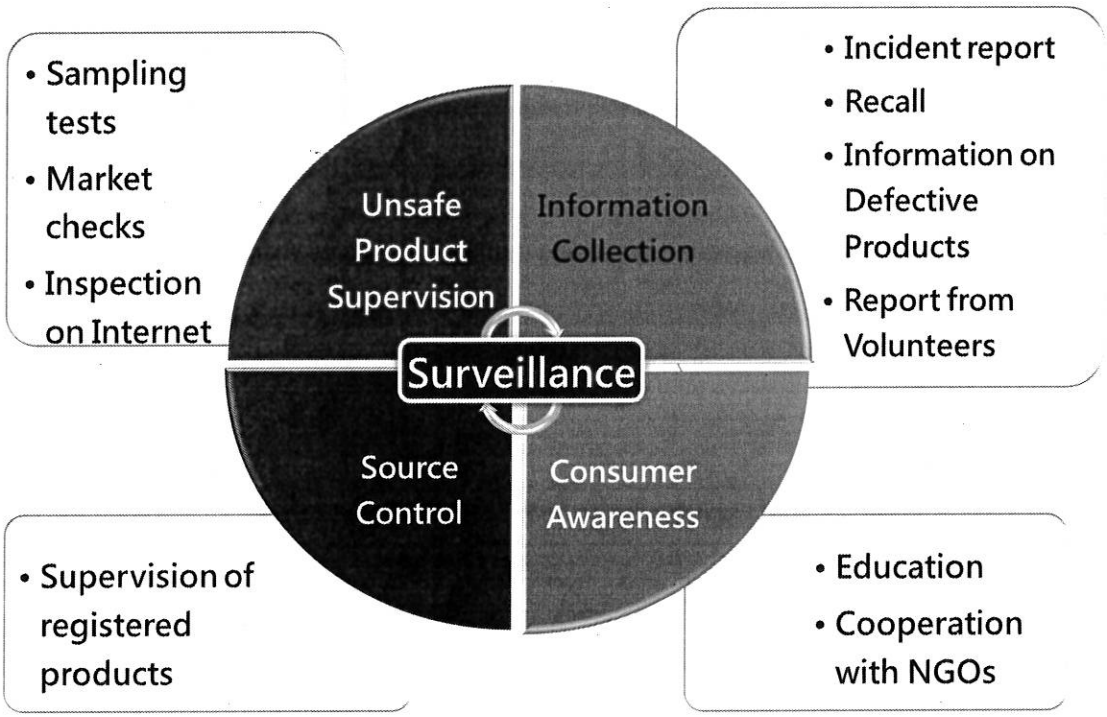

圖 5：臺灣消費性商品市場監督管理機制

（二）Q&A：

1. Q：歐盟與臺灣不同，歐盟是自由市場，沒有前市場管制，而臺灣有前市場管制，若要完成檢驗才能上市會有時間落差（time delay），對

於想要進入臺灣市場的外商可會有商機喪失，是否會影響外商進入臺灣市場的意願？（Ivan Hendirkx）

A：臺灣是島國，仰賴進出口貿易，相較於歐洲是共同市場，許多商品可以自由流通，商品管理的方式就不同；此外，消費習慣與廠商的自我控管意識不同，所以在臺灣政府必須要確保商品在進入市場前必須完成檢驗程序以確保消費者安全。關於時效部分，以現行最常使用的驗證登錄制度，證書期限是三年，三年期間內可以隨時進口商品，即可減少上市的時間落差，但是廠商仍必須確保都能符合檢驗規定。

2. Q：臺灣一年分配在市場監督的預算有多少? 在阿拉伯聯合大公國，雖然市場監督與實驗室同一個組織底下，執行購樣檢測也會收取費用。（Ali Al Ramlah,Senior Specialist of Emirates Authority for Standardization & Metrology, UAE）；預算的評估對 GSO 很重要，因為 GSO 現在才要開始執行後市場監督計畫，預算多寡才有辦法評估要如何執行)，另外，罰鍰的收入也會算在預算來源嗎?（Ivan Hendirkx）

A：標準檢驗局每年執行購樣檢測計畫的預算約新臺幣 250 萬元（約當美金 8 萬 4,000 元），市場檢查無須費用，檢測部分若由標準檢驗局之檢測單位執行則無需檢測費用，因此在預算資源有限下，就會針對高風險或流行性商品進行購樣檢測計畫。另罰鍰收入不直接列入當年的預算來源。

3. Q：臺灣如何執行網路檢查? （Ali Al Ramlah）

A：每月於網路購物及拍賣平臺搜尋不同之應施檢驗商品，如網頁資訊未標示商品檢驗號碼、標識等足以辨識該商品已符合商品檢驗規定者，將通知賣家重新審視所販售商品有無完成檢驗，若未完成檢驗程序則請自行下架。（直接以電腦實際操作予現場人員看）

4. Q：臺灣的市場監督機制是否有相關作業程序來確保市場監督能被有效執行且不會有例外。（Ivan Hendirkx）

A：臺灣的市場監督作業程序是依據商品檢驗法(針對應施檢驗商品)來制訂相關作業程序，其他法源依據則是消費者保護法(針對一般消

費性商品)，每年會針對相關作業程序執行市場監督措施，年底則會針對當年度高風險或流行性商品(高違規率)，列為下一年度的加強商品。

5. Q：由誰、如何決定什麼商品要列為強制檢驗商品？（Abdesselam Benyaich）

A：由標準檢驗局評估後再公告實施哪些商品要列入強制檢驗商品範圍。商品是否列入應施檢驗商品會多方考量商品的風險與可能造成的傷害。舉例來說，塑膠軟質桌墊目前不是應施檢驗商品，但根據簡報中所示的資料，近 3 年違規率仍高，且考量所含的塑化劑可能造成孩童發育的危害，標準檢驗局已經評估將其列入應施檢驗商品，預計明年將會列為應施檢驗商品。

肆、出國心得及建議

一、藉由持續派員參與海灣國家組織活動，增加合作深度

海灣國家目前尚未建立完整商品後市場監督機制，雖目前已將玩具與低電壓商品列為檢驗，惟各海灣國家組織間的檢驗標準、實驗室、後市場監督作法尚在建置中，仍須仰賴歐美國家協助，海灣國家組織因極力想發展完整商品監管制度（從標準、檢驗、市場監督等），而我國已有一套完整的市場監督機制，若 GSO 國家有相關研討會議，建議可持續派員參加交流，增加雙方合作深度。且 GSO 辦理研討會或訓練課程多邀集各國專家與會授課，藉由研討會，可以了解海灣國家對於商品實質安全的重視與他國對於商品後市場管理制度之實際做法

二、未來可評估採行完整的商品風險評估機制，強化整體市場商品安全

因歐盟沒有前市場管理，所以其後市場監督方面相當程度仰賴廠商的「自制與自主管理」，如商品於進入市場後發現有危害性，經通報後，歐盟得依商品瑕疵所引發的風險，藉由風險評估機制(risk assessment)，針對不同個案採行適當處置措施，並即時更新商品風險資料庫，有效降低商品風險與保障消費者使用安全。

反觀我國，由於商品檢驗法之規定，對於違反上市前程序規定者，無論商品是否具危害性，皆應處以罰鍰。因此，市場監督方面仍以取締程序違規為主，主要檢查是否貼附商品檢驗標識。民眾反映案件中，也以反映程序違規為主，反映商品不安全者則占少數。標檢局花費大量人力處理程序違規問題，卻不必然會降低商品風險。因為有上市前檢驗並不代表市場上的商品必然安全；而未為上市前檢驗的商品，亦不代表其必然有危害性[10]。雖商品檢驗法於 96 年修正時，仿效歐美國家增訂商品事故通報制度，是我國開始著重商品瑕疵的轉捩點。惟因目前商品事故強制通報範圍較小，因此大體而言，標檢局的市場監督人力仍著重於程序違規而非商品實質安全。

因此，若為更著重商品實質安全，可仿效歐盟建立完整的商品風險

[10] 黃于稹 出席經濟合作暨發展組織(OECD)/國際消費商品安全論壇(ICPSC)2014 年全球論壇會議及國際消費商品健康安全組織(ICPHSO)2014 年國際研討會報告，2014 年 9 月 18 日，頁 24。

評估資料庫，有一致性的標準與完整的資料庫可供業者或市場監督人員遵循，完整的資料庫可作為相關商品處置作為的依循，減少人為主觀的判定商品風險與危害性，與國際作法接軌，讓我國商品監督機制趨於完備。

伍、附錄

附錄一、感謝狀

Sustainable partnership شراكة مستدامة

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لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization

Certificate of Appreciation

The GCC Standardization Training Center expresses its full appreciation, thanks & gratitude to

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in honor of the outstanding performance and dedication in presenting the training course titled:

Good Market Surveillance Practices

Organized in cooperation with Public Authority for Industry – Kuwait

Kuwait | 3 Day(s) | 02-04 October 2017

GSO Secretary General

H.E. Nabil A. Molla

Awarded on 02. OCT.2017

How to use the RAPEX Risk Assessment Guidelines Application

Table of Contents

Welcome to the RAG application

This document provides you help for the use of the RAPEX Risk Assessment Guidelines (RAG) application, which is accessible via the internet at http://europa.eu/sanco/rag/.

The application helps you when applying the risk assessment guidelines for non-food consumer products that were published in early 2010 as part of the RAPEX Guidelines[1]. You have access to the RAPEX Guidelines through the "Help" menu point of the application, the risk assessment guidelines start on page 33 (bottom) of the Official Journal issue that pops up.

The application is the property of the European Commission. By entering it, you agree to use it in accordance with the European Commission policies, local laws and regulations.

The application was thoroughly tested and should provide results that are in compliance with the RAG. However, the Commission does not represent or warrant that the application will be error free. The appropriate use of the application is entirely under your responsibility.

Should you have any suggestions for improving the application, please go to the application's "About" and click on the "*WebMaster*". Or send an e-mail directly to SANCO-RAPEX-RAG@ec.europa.eu. Your suggestions may be included in a future version of the application.

The application does not register any of your data. Therefore, please save your data from time to time in order not to lose them. They will be stored on your computer in the form of a txt file.

How to prepare a risk assessment

General Information and Overview

How to use the application

You should type the relevant information into the different fields. The clearer your information is, the easier it will be understood. You should take particular care when you provide the description of the product of which you are assessing the risk.

The two coloured fields in the lower half of the screen, "Product risks – Overview" and "Scenario summary", will be automatically filled in by the application once you have completed your risk assessment.

When you have put in all the information, click on the button "Create a scenario" in the bottom-left corner. This will lead you to the part on scenario building.

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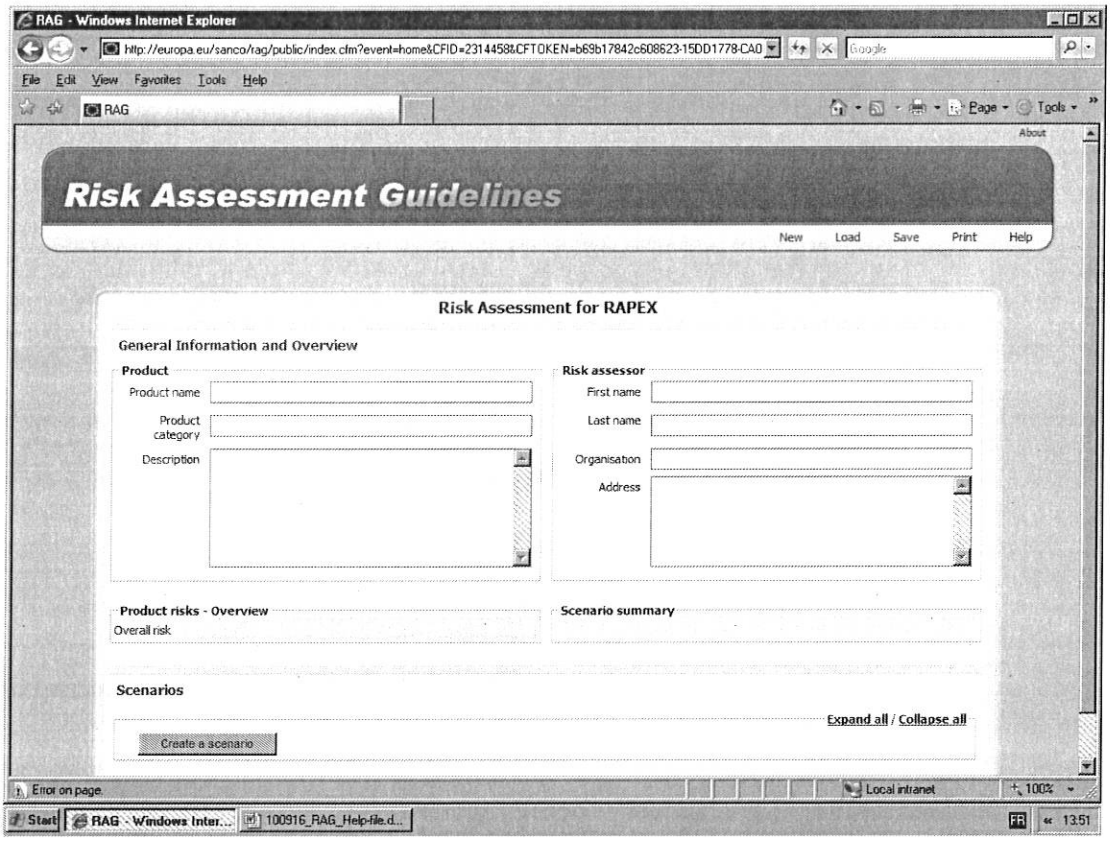
[1] Commission Decision 2010/15/EU laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive). OJEU L 22, 26.1.10, p. 1.



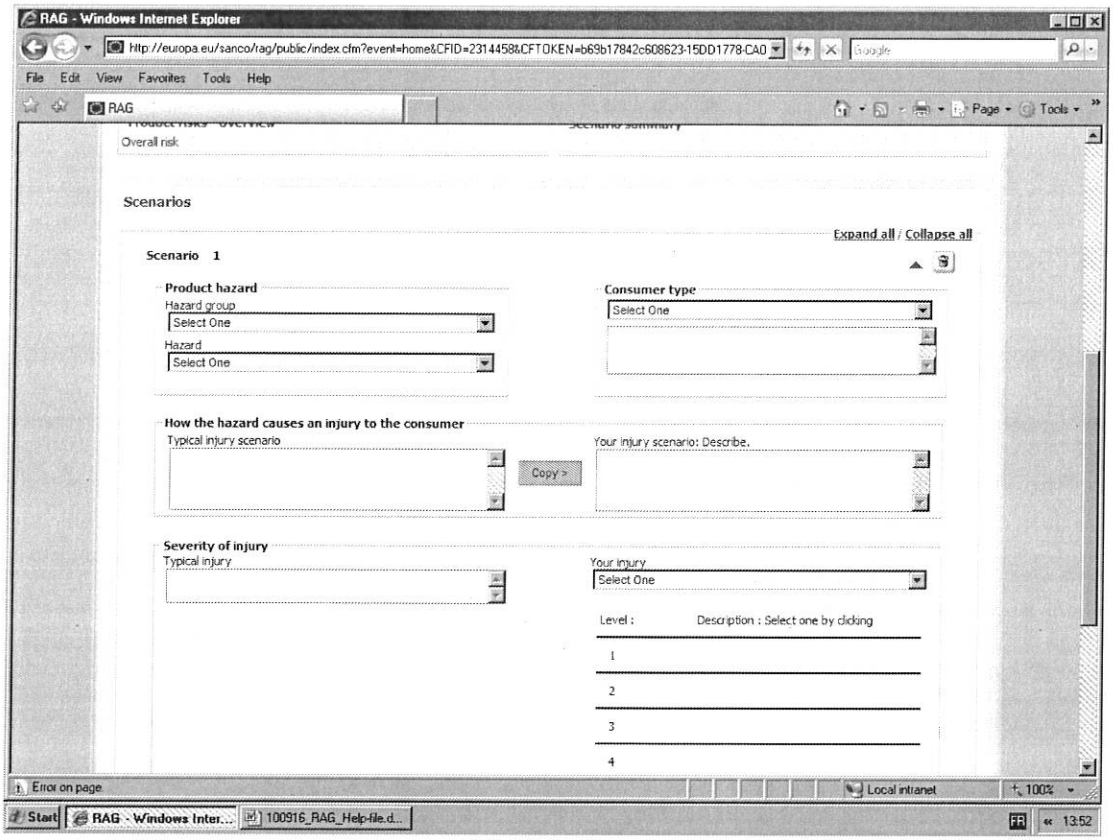
What do the RAPEX Risk Assessment Guidelines say?

Section 3.1 of the RAG tells you what is important when you describe your product. In short, describe it unambiguously: Will the risk assessment concern the entire product or only a part of it (since only that part could pose a risk)? Are there any labels, in particular warning labels? Does the product have to be assembled by the consumer? May a product hazard appear during the life-time of the product? May the product become risky during its life-time although it was not used? All these elements, and perhaps others, should be described clearly in order that the assessment can be easily understood.

Scenarios

How to use the application

The Scenarios dialogue shows you all the elements that you need to put in for the risk assessment of your product: Hazard group, product hazard and consumer type. You should then formulate your injury scenario and select the severity of injury as well as the respective probability(ies) (below the lower end of the following screen shot).



What do the RAPEX Risk Assessment Guidelines say?

A scenario is the description of how the intrinsic product hazard causes an injury to the consumer. You anticipate such a scenario, including all its components, and write it down in the application in order to determine the risk of the product in that scenario.

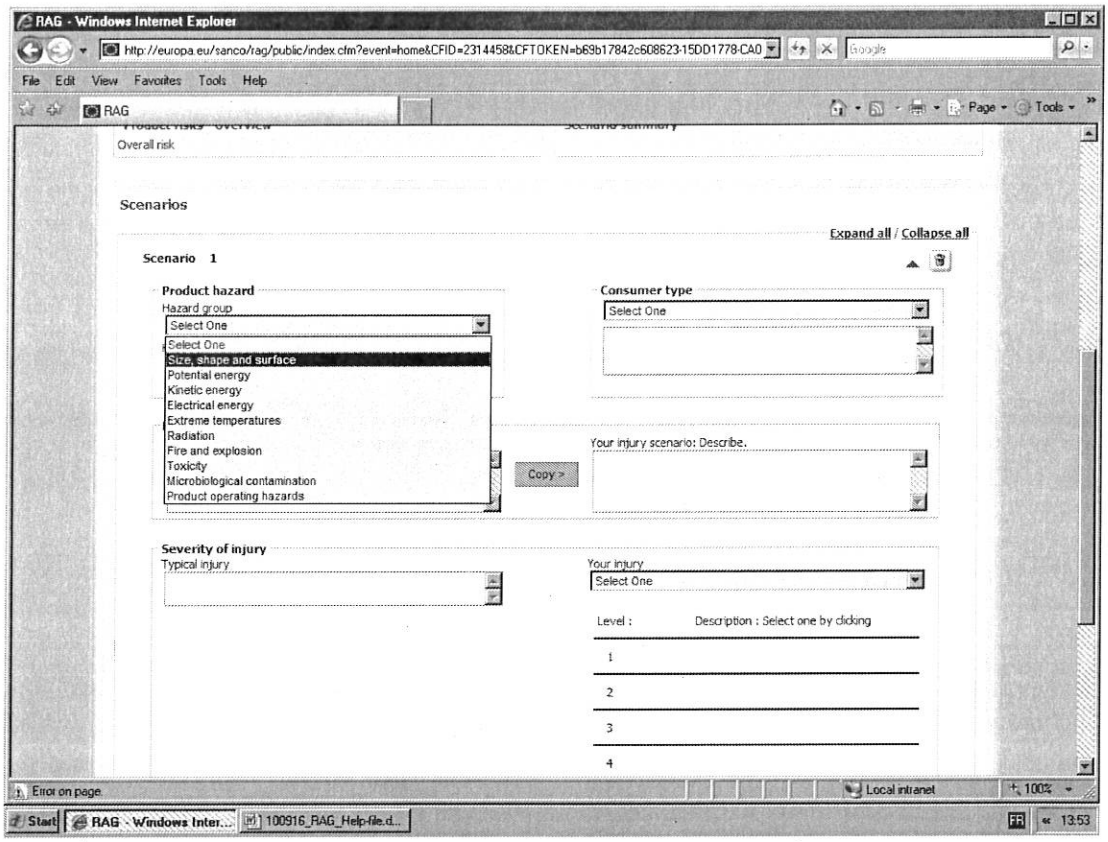
You should eventually develop several scenarios and determine their risks, in order to take the highest risk as "the risk" of the product.

Section 3.4 of the guidelines tells you what is important when you develop your injury scenario(s). In short, your injury scenario(s) should neither be too short nor too long; perhaps some 3 to 5 sentences are sufficient. This requires some practice. - To make things easier, you could start with a scenario in which the intended user uses the product in the way it is foreseen. You could then create scenarios with a non-intended user, or with a non-intended (but still reasonably foreseeable) way of using the product. Finally, when the product has several hazards, you should anticipate scenarios for each of the hazards. Your final aim should always be to identify the highest risk of all scenarios as "the risk" of the product.

Product hazard

How to use the application

To select a product hazard, you should first select a "Hazard group" from the drop-down box, and then the hazard itself from the "Hazard" drop-down box immediately below. You will see that, as soon as you selected a hazard, the boxes for the "Typical injury scenario" and the "Typical injury" further below fill themselves with typical examples that should help you at further stages of your risk assessment.


RAG - Windows Internet Explorer
http://europa.eu/sanco/rag/public/index.cfm?event=home&CFID=2314458&CFTOKEN=b69b17842c608623-15DD1778-CA0
File Edit View Favorites Tools Help
RAG
Page Tools
Overall risk
Scenarios
Expand all / Collapse all
Scenario 1
Product hazard
Hazard group
Select One
Select One
Size, shape and surface
Potential energy
Kinetic energy
Electrical energy
Extreme temperatures
Radiation
Fire and explosion
Toxicity
Microbiological contamination
Product operating hazards
Consumer type
Select One
Copy >
Your injury scenario: Describe.
Severity of injury
Typical injury
Your injury
Select One
Level :
Description : Select one by clicking
1
2
3
4
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
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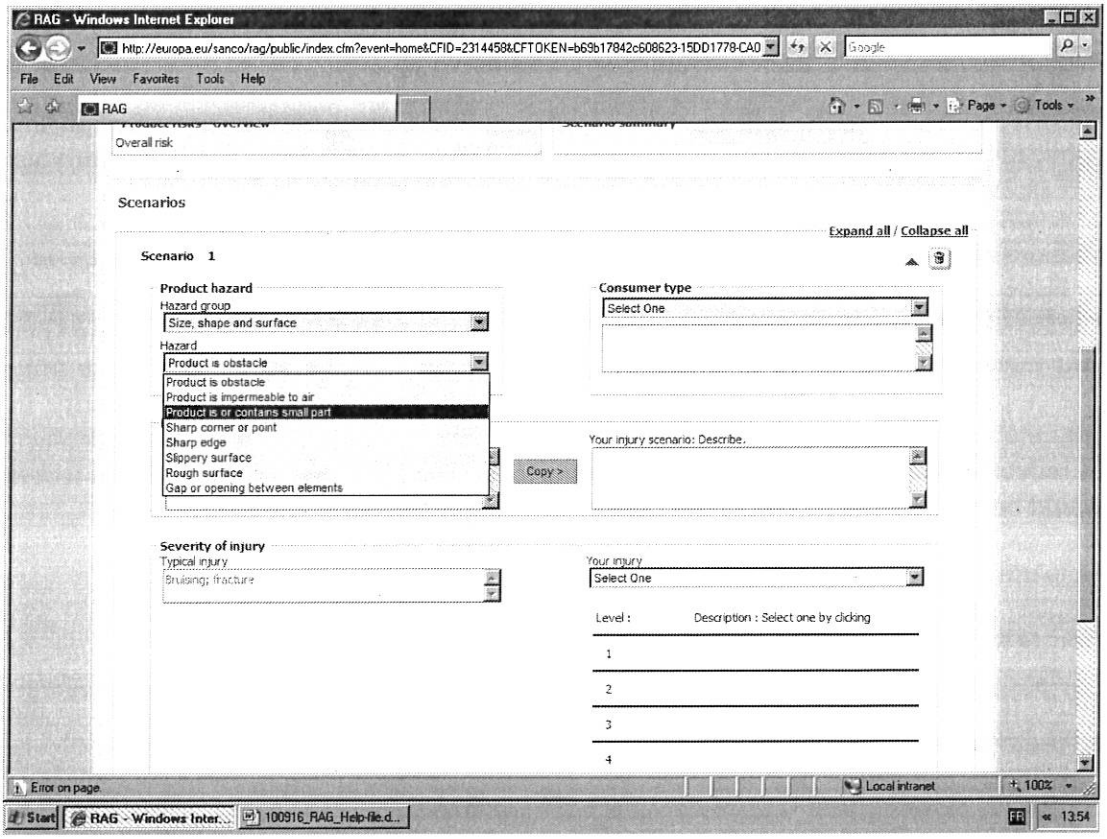
13:53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File Edit View Favorites Tools Help
RAG
Page Tools
Overall risk
Scenarios
Expand all / Collapse all
Scenario 1
Product hazard
Hazard group
Size, shape and surface
Hazard
Product is obstacle
Product is obstacle
Product is impermeable to air
Product is or contains small part
Sharp corner or point
Sharp edge
Slippery surface
Rough surface
Gap or opening between elements
Consumer type
Select One
Copy >
Your injury scenario: Describe.
Severity of injury
Typical injury
Bruising; fracture
Your injury
Select One
Level :
Description : Select one by clicking
1
2
3
4
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
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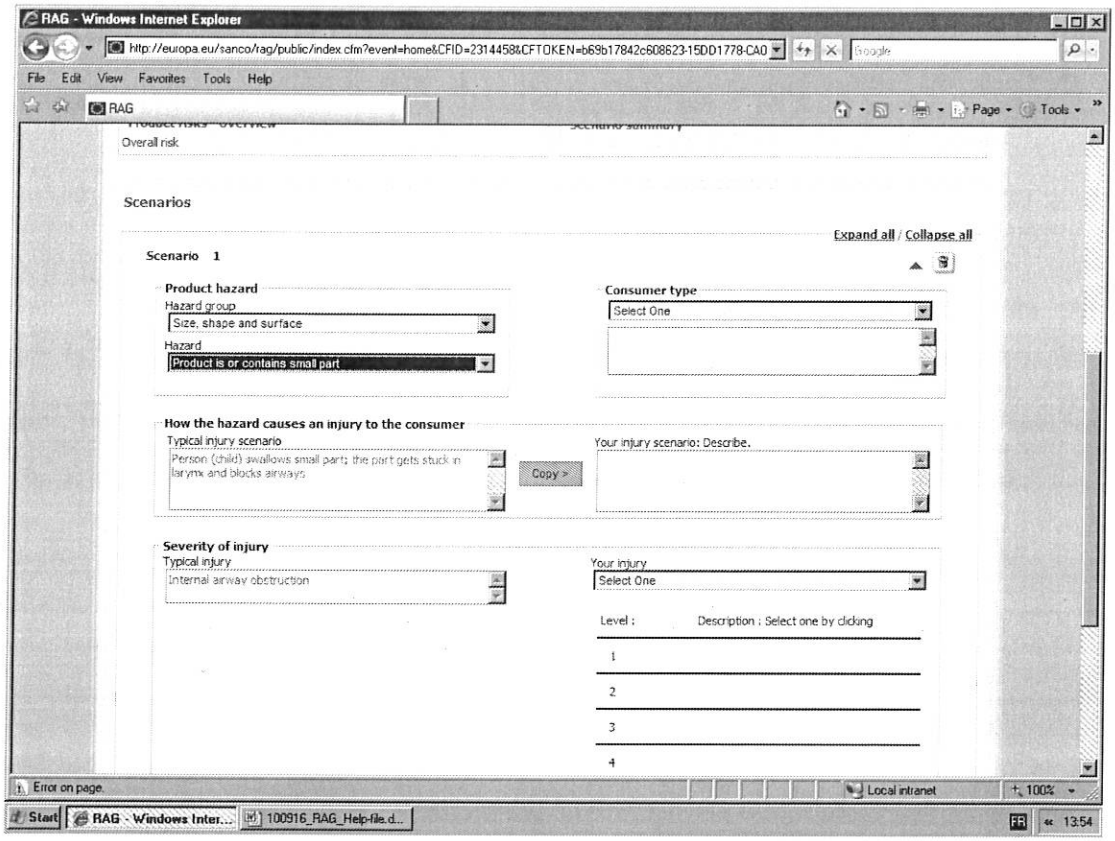
13:54



What do the RAPEX Risk Assessment Guidelines say?

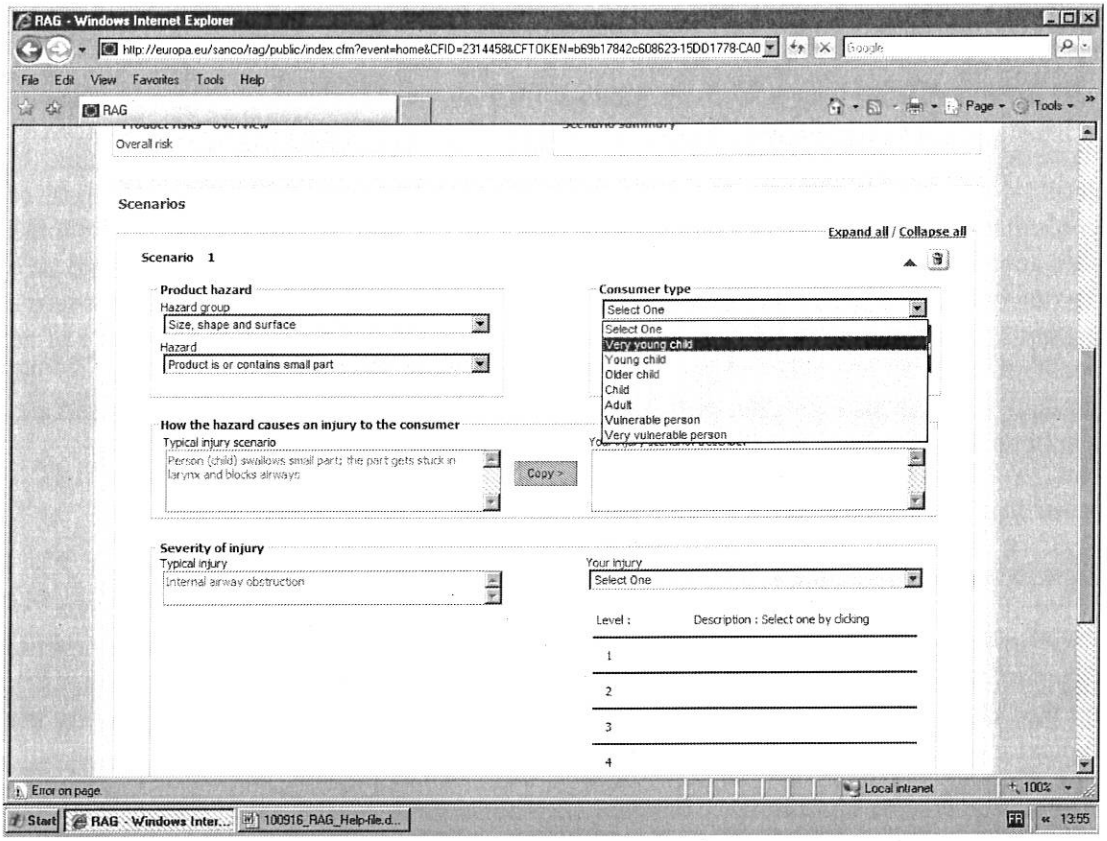
Hazard groups, hazards, typical injury scenarios and typical injuries presented in the application truly reflect table 2 of the guidelines. Take them as an orientation (!) for your risk assessment(s).

Section 3.2 of the guidelines tells you what is important in relation to the product hazard. In short, each hazard of a product should be investigated in an own risk assessment (better: in several risk assessments). Should a single hazard cause several injuries in your injury scenario, you should estimate the severity of all injuries together in order to truly reflect the hazard. However, you should never add up injuries that you identify in separate scenarios. – Also products which have no intrinsic hazard can cause a risk, such as reflective jackets that do not reflect sufficiently. The consumer wearing such a jacket would be at risk since he would not be seen sufficiently, in particular at night.

Consumer type

How to use the application

Select the "Consumer type" that you wish to include in your risk assessment from the drop-down box.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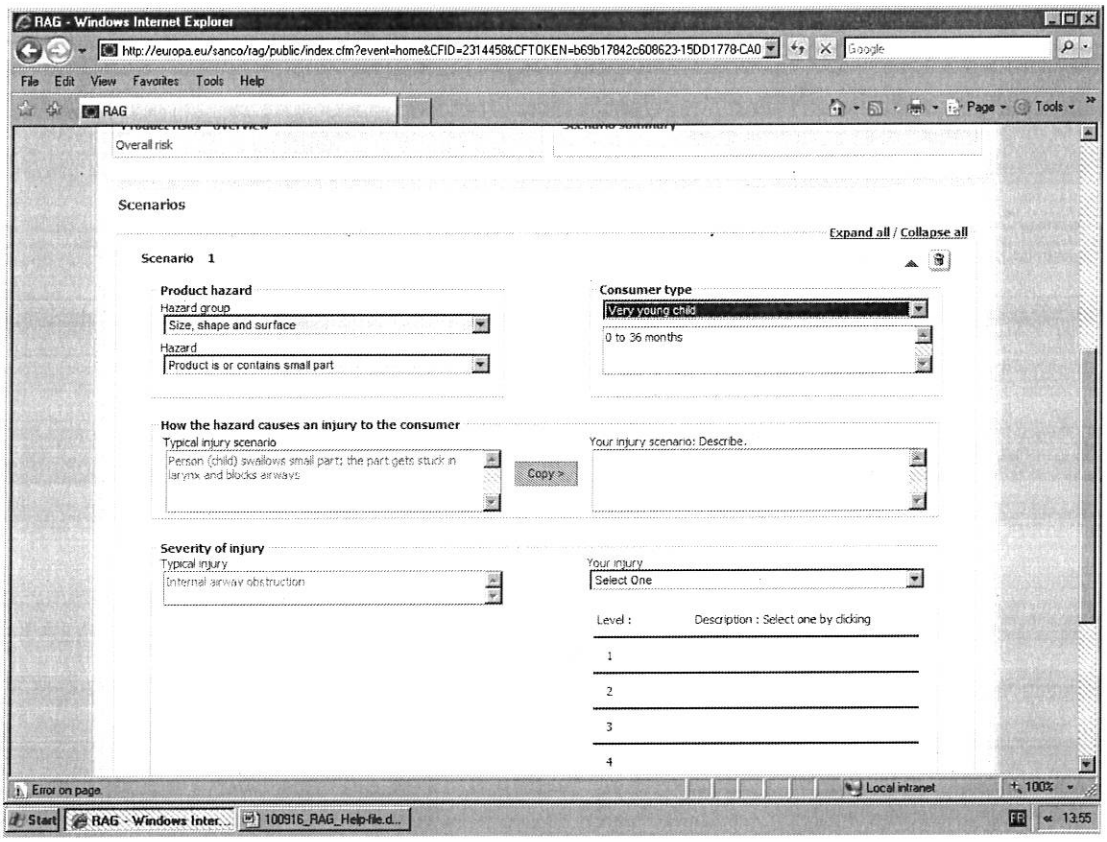
http://europa.eu/sanco/rag/public/index.cfm?event=home&CFID=2314458&CFTOKEN=b69b17842c608623-15DD1778-CA0
File Edit View Favorites Tools Help
RAG
Page Tools
Overall risk
Scenarios
Expand all / Collapse all
Scenario 1
Product hazard
Hazard group
Size, shape and surface
Hazard
Product is or contains small part
Consumer type
Select One
Select One
Very young child
Young child
Older child
Child
Adult
Vulnerable person
Very vulnerable person
How the hazard causes an injury to the consumer
Typical injury scenario
Person (child) swallows small part; the part gets stuck in larynx and blocks airways
Copy >
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Select One
Level :
Description : Select one by clicking
1
2
3
4
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
100916_RAG_Help-file.d...
FR
13:55


RAG - Windows Internet Explorer
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File Edit View Favorites Tools Help
RAG
Page Tools
Overall risk
Scenarios
Expand all / Collapse all
Scenario 1
Product hazard
Hazard group
Size, shape and surface
Hazard
Product is or contains small part
Consumer type
Very young child
0 to 36 months
How the hazard causes an injury to the consumer
Typical injury scenario
Person (child) swallows small part; the part gets stuck in larynx and blocks airways
Copy >
Your injury scenario: Describe.
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Select One
Level :
Description : Select one by clicking
1
2
3
4
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
100916_RAG_Help-file.d...
FR
13:55

What do the RAPEX Risk Assessment Guidelines say?

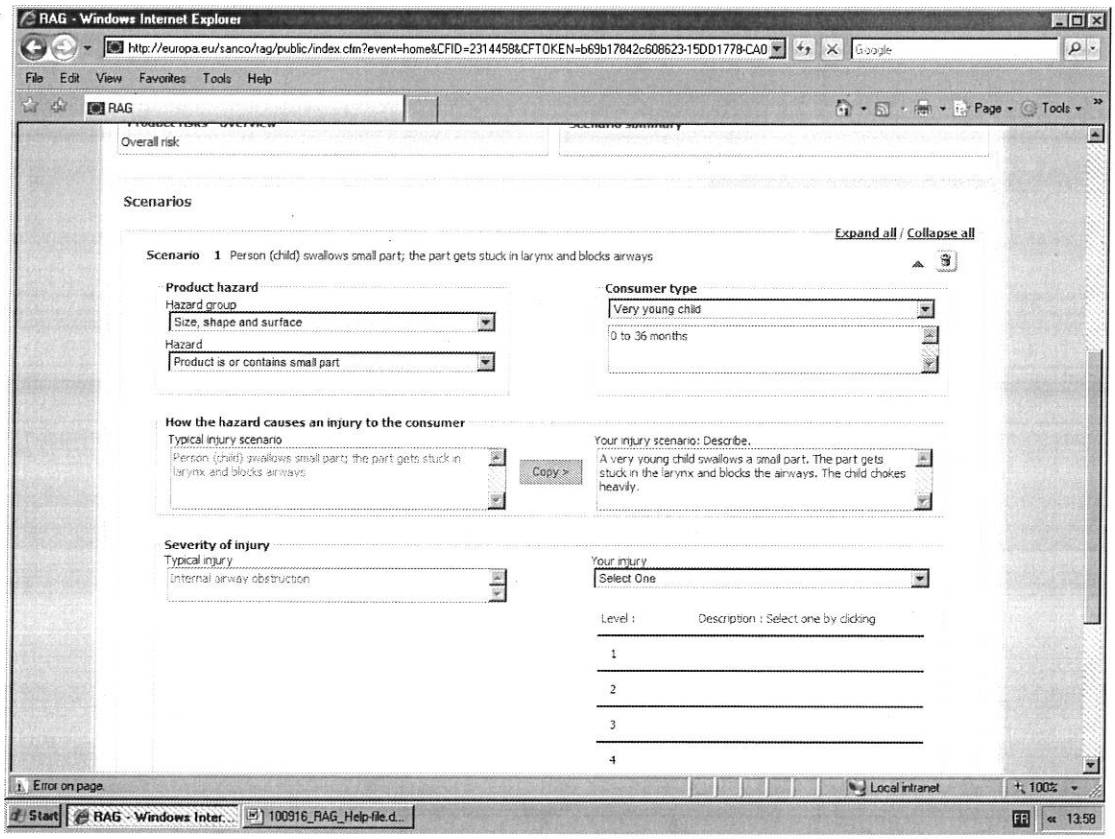
The consumer types presented in the application truly reflect table 1 of the guidelines.

Section 3.3 of the guidelines tells you what is important in relation to consumers. In short, you should always prepare several risk assessments with several types of consumers, including vulnerable consumers such as children or the elderly. You should also consider uses which are not intended, but "reasonably foreseeable". You should take account of the frequency and duration of use, of the hazard recognition by the user in the presence/absence of warnings, of the user's protective behaviour, including in case of an accident, and of the user's cultural background which may influence the use of the product. - Please also consider possible bystanders, such as when a chain saw is used and a splinter flying around injures a child that is watching!

Your injury scenario

How to use the application

Type in the injury scenario that you intend to evaluate with your risk assessment. If the "Typical injury scenario" to the left-hand side of the box is a good model for you, click on the "Copy >" button between the two boxes to take it over. You can then modify the typical injury scenario according to your needs.



You can also delete a scenario, namely by clicking on the waste bin in the top right corner of the scenario. This deleted scenario will appear as a hyphen ("-") in the "Scenario summary" box at the top of the application (see higher above). To get rid of the hyphen, please save your risk assessment and load it again into the application.

What do the RAPEX Risk Assessment Guidelines say?

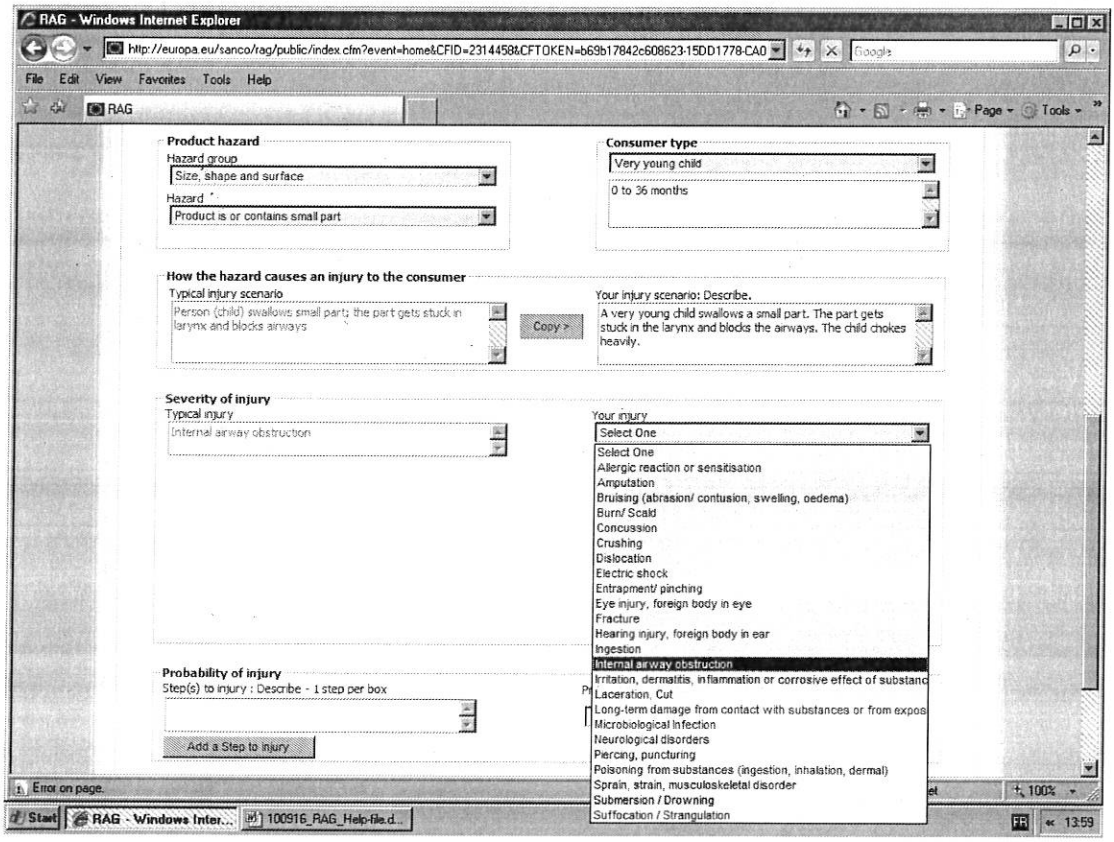
Section 3.4 of the guidelines tells you what is important when you develop your injury scenario. See also above in section "Scenarios".

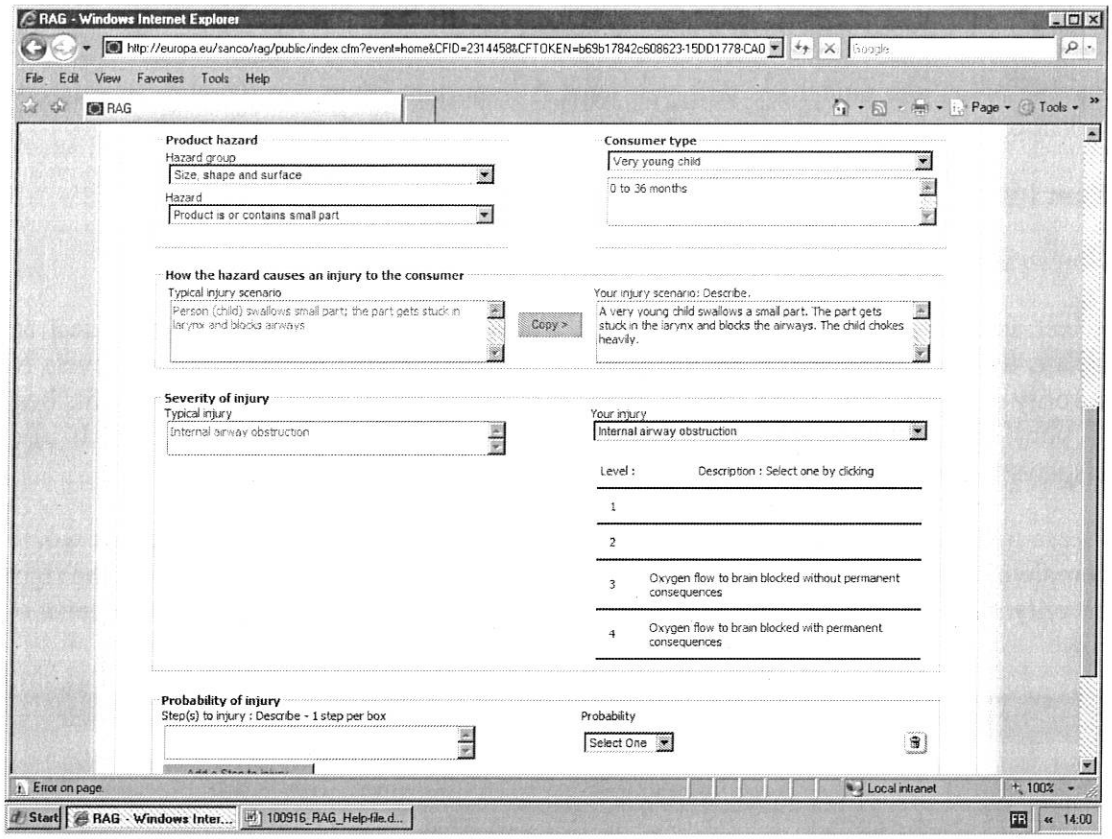
Your injury

How to use the application

Select an injury from the drop-down box. You will see that, as soon as you select an injury, the four lines below fill themselves with descriptions of the available levels of severity of injury (which may be less than four). Select the severity of injury that fits best to your scenario, you will see hat the application highlights your selection. It also displays the severity of injury level close to the bottom of the page.

Please take the proposed injuries only for orientation! There can be no table that would completely list all possible injuries! Most important is, however, that you select the right severity of injury, because the application uses the severity when it calculates the level of risk!




RAG - Windows Internet Explorer
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File Edit View Favorites Tools Help
RAG
Page Tools
Product hazard
Hazard group
Size, shape and surface
Hazard
Product is or contains small part
Consumer type
Very young child
0 to 36 months
How the hazard causes an injury to the consumer
Typical injury scenario
Person (child) swallows small part; the part gets stuck in larynx and blocks airways
Copy >
Your injury scenario: Describe.
A very young child swallows a small part. The part gets stuck in the larynx and blocks the airways. The child chokes heavily.
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Internal airway obstruction
Level : Description : Select one by clicking
1
2
3 Oxygen flow to brain blocked without permanent consequences
4 Oxygen flow to brain blocked with permanent consequences
Probability of injury
Step(s) to injury : Describe - 1 step per box
Probability
Select One
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
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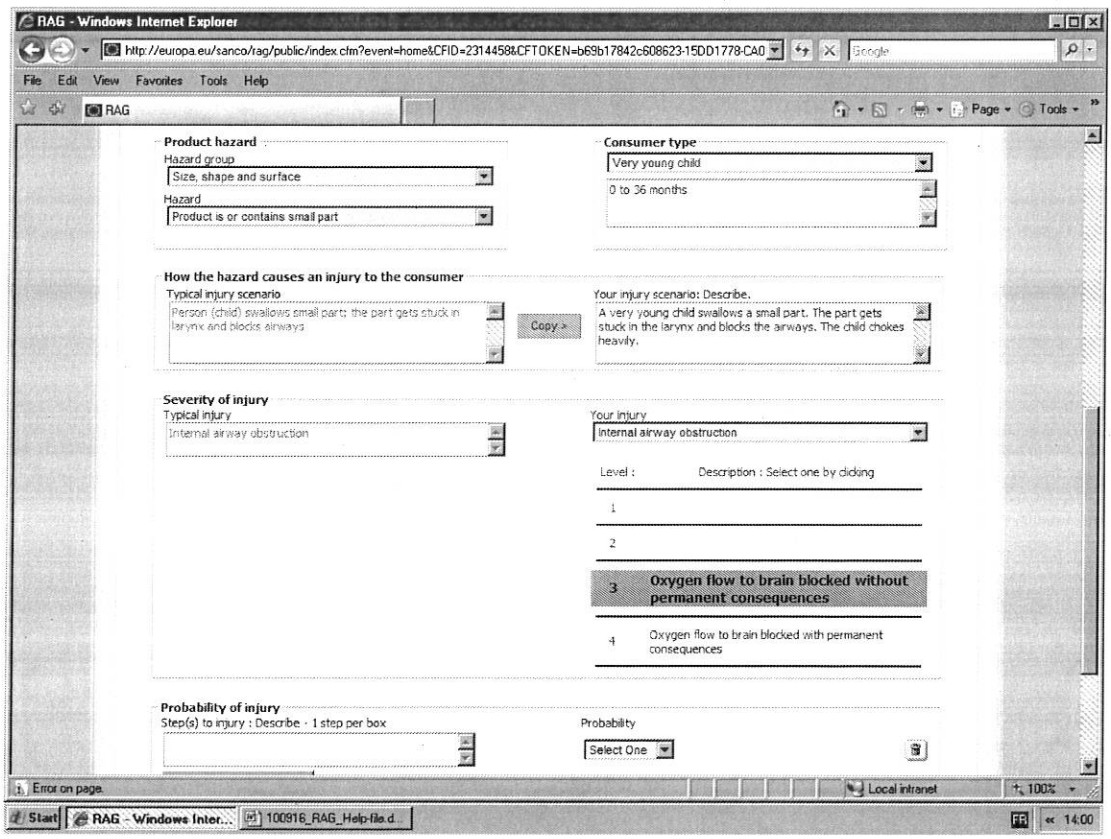
FR
14:00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File Edit View Favorites Tools Help
RAG
Page Tools
Product hazard
Hazard group
Size, shape and surface
Hazard
Product is or contains small part
Consumer type
Very young child
0 to 36 months
How the hazard causes an injury to the consumer
Typical injury scenario
Person (child) swallows small part; the part gets stuck in larynx and blocks airways
Copy >
Your injury scenario: Describe.
A very young child swallows a small part. The part gets stuck in the larynx and blocks the airways. The child chokes heavily.
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Internal airway obstruction
Level : Description : Select one by clicking
1
2
3 Oxygen flow to brain blocked without permanent consequences
4 Oxygen flow to brain blocked with permanent consequences
Probability of injury
Step(s) to injury : Describe - 1 step per box
Probability
Select One
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
100916_RAG_Help-file.d...
FR
14:00

What do the RAPEX Risk Assessment Guidelines say?

Section 3.5 of the guidelines tells you what is important when you assign the severity of injury in your injury scenario. The application truly reflects table 3 of the guidelines.

In short, the injury and its severity depend on the type and "power" of the hazard, on the length of time that it impinges on the consumer, on which body parts are injured, on what impact the hazard may have on several body parts, and on the type and behaviour of the consumer. When you prepare several risk assessments, do not sum up the injuries in the separate scenarios. However, should your injury scenario lead to several injuries, estimate the severity of injury of all these injuries together.

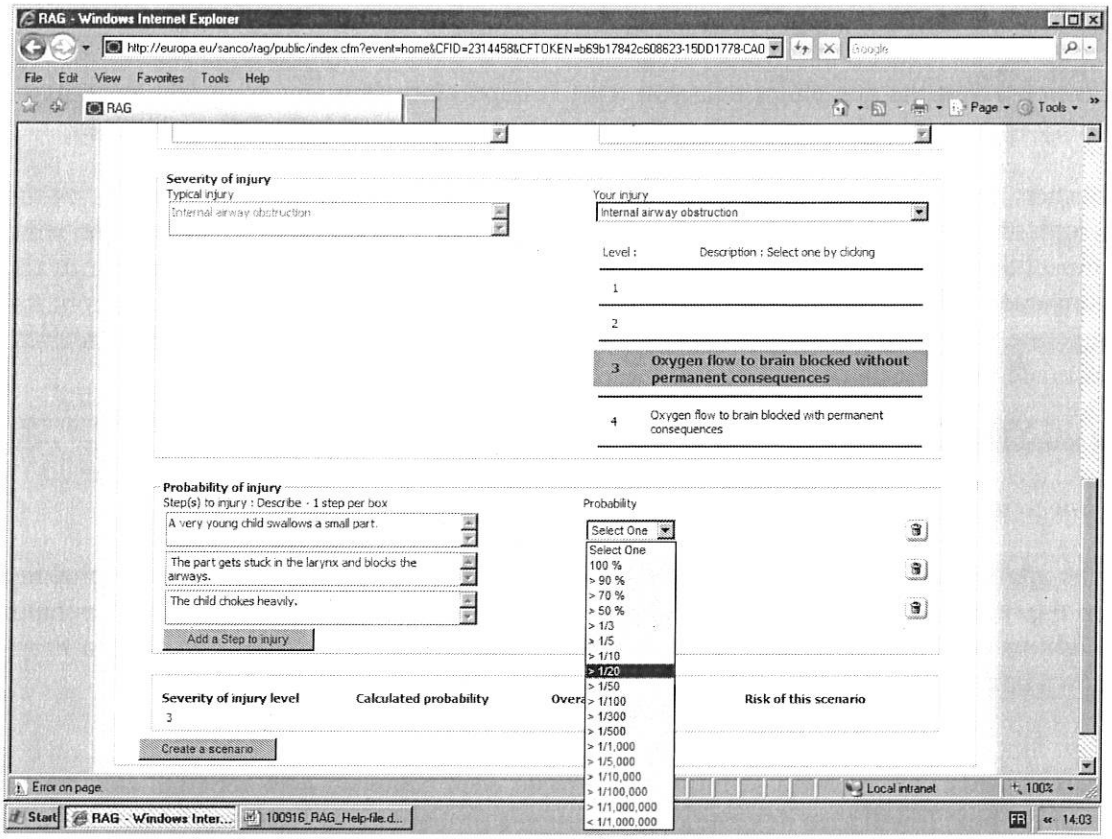
Probability of injury

How to use the application

The application allows you to divide your injury scenario into several steps by clicking on the button "Add a Step to injury" and typing in a step into each box that is opening. Right to each box, you can then select the probability for the single step from a drop-down box.

Tip: Since your injury scenario will comprise about 3 to 5 sentences representing each a step towards the consumer's injury, copy/paste each sentence as a separate step into a separate box. It will then be quite easy to assign a probability to each step.

Once you have assigned a probability to each step, the application will calculate and display the "Calculated probability" (which is the multiplication of the probabilities that you assigned to the different steps of your injury scenario), the "Overall probability" (which is the level of probability "allowed" in table 4 of the risk assessment guidelines) and the "Risk of this scenario" (which results from the combination of the severity of injury with the overall probability).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File Edit View Favorites Tools Help
RAG
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Internal airway obstruction
Level :
Description : Select one by clicking
1
2
3
Oxygen flow to brain blocked without permanent consequences
4
Oxygen flow to brain blocked with permanent consequences
Probability of injury
Step(s) to injury : Describe - 1 step per box
Probability
A very young child swallows a small part.
The part gets stuck in the larynx and blocks the airways.
The child chokes heavily.
Select One
Select One
100 %
> 90 %
> 70 %
> 50 %
> 1/3
> 1/5
> 1/10
> 1/20
> 1/50
> 1/100
> 1/300
> 1/500
> 1/1,000
> 1/5,000
> 1/10,000
> 1/100,000
> 1/1,000,000
< 1/1,000,000
Add a Step to injury
Severity of injury level
Calculated probability
Risk of this scenario
3
Create a scenario
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
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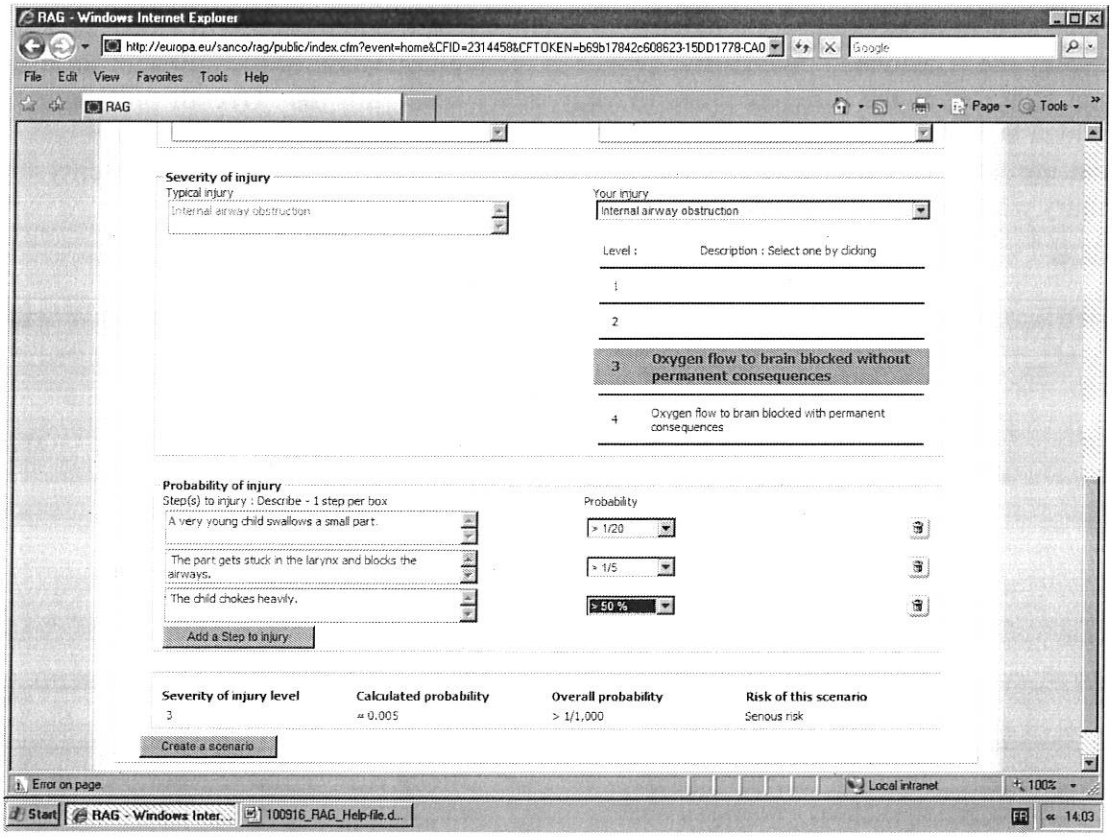
14:03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File Edit View Favorites Tools Help
RAG
Severity of injury
Typical injury
Internal airway obstruction
Your injury
Internal airway obstruction
Level :
Description : Select one by clicking
1
2
3
Oxygen flow to brain blocked without permanent consequences
4
Oxygen flow to brain blocked with permanent consequences
Probability of injury
Step(s) to injury : Describe - 1 step per box
Probability
A very young child swallows a small part.
> 1/20
The part gets stuck in the larynx and blocks the airways.
> 1/5
The child chokes heavily.
> 50 %
Add a Step to injury
Severity of injury level
Calculated probability
Overall probability
Risk of this scenario
3
≈ 0.005
> 1/1,000
Serious risk
Create a scenario
Error on page.
Local intranet
100%
Start
RAG - Windows Inter...
100916_RAG_Help-file.d...
14:03

What do the RAPEX Risk Assessment Guidelines say?

The application truly reflects table 4 of the guidelines.

Section 3.6 of the guidelines tells you what is important when you assign the Probability of injury, and section 3.7 tells you about the Determination of risk. In short, it is not always easy to estimate the probability, but when your injury scenario is split into several steps, it should be easier to assign a probability to each single step. In addition, when you are hesitant about probabilities, just vary the probabilities and see whether the risk changes or not. Such a "sensitivity analysis" will show you whether it is necessary to estimate a probability with great precision (namely when the risk level changes with a small change of the probability), or whether a roughly assumed probability is sufficient (namely when the risk level does not change when you change the probability).

New – Load – Save – Print – Help

The application allows you to "wipe away" the risk assessment that you have currently on screen in order to put in a **New** risk assessment. The feature works as usual in other computer applications, just try it out.

You can also **Load** a risk assessment into your computer that you have previously saved on your hard disk. Also this feature works as usual, try it out.

Please **Save** your risk assessment regularly while preparing it. This ensures that you do not lose any of the data that you have entered.

Note that the application saves your data only on the hard disk of your computer (or network drive) according to your choice. Nobody but you is therefore responsible for saving your data, and nobody but you can see the data you enter in the application.

Therefore please save your data as often as you deem necessary, but also feel free to experiment with any data that you would like to try out. This will provide you experience in risk assessment which may be invaluable.

Print your risk assessment whenever you want to document it on paper. The application prints your risk assessment in the form of a pdf file which you can also save as any other pdf file. Just try it out.

Note that Print prints all your injury scenarios. Should you have deleted a scenario in the course of preparing your risk assessment (for example because you deemed it unsuitable), a hyphen ("-") will be printed which represents the deleted scenario. To get rid of the hyphen, please save your risk assessment, load it again into the application, and then print it.

The **Help** feature provides you access to this Help file and to the RAPEX Guidelines as published in the Official Journal.

And now – good luck and every success!

ANNEX A – EXAMPLES OF MECHANISMS TO BE USED IN CROSS-BORDER MARKET SURVEILLANCE PROJECTS

A.1 Introduction

According to the GPSD, market surveillance programmes must be effective and based on risks assessment. At present, in all Member States and connected countries, market surveillance programmes are planned and executed. However, programmes and projects are planned individually, often without any connection with the programmes in other Member States.

The market for consumer products is global. Hence, market surveillance needs to have a broader focus than merely the home territory or even existing cooperation between neighbouring Member States. Often, products are brought on the market by a producer (manufacturer or importer) operating Europe-wide rather than by many domestic importers. Therefore, the most efficient way to solve a safety issue with a product is to co-operate cross-border so that the authority in the Member State where the producer is based resolves the issue together with the producer and the problem is taken care of at the source (the home authority principle).

Moreover, market surveillance faces challenges associated with a general outsourcing of production to third countries which necessitates a more intense control at the external borders and makes it more difficult for the authorities to perform controls of the production process. Such controls may be most efficiently carried out in cooperation between the Member States because industry outside the EU tends to see the European market as one single market and not one regulated by many individual authorities.

Furthermore, non-food consumer products do not have an expiry date, which means that they can be stored for a long time. Examples are seen where products that were banned in one country are moved to other countries to be sold after some time when the story has been forgotten. This is also a situation that can only be resolved through cross-border cooperation and exchange of information.

Market surveillance's aim to protect citizens against unsafe products necessitates cross-border cooperation to achieve an effective system of supervision and enforcement.

A.1.1 Ways to cooperate

Several forms of cooperation in market surveillance are possible and can be used separately or concurrently. However, methods and structures of cooperation are only successful when participants are proactive and really willing to work together. The motivation of market surveillance officers and their natural behaviour to think cross-border are the basis for a successful market surveillance system and optimal protection of citizens.

A.1.1.1 Cooperation in case of incidents (reactive)

RAPEX

If a dangerous or unsafe product is detected on the market, market surveillance officers must inform their colleagues in other countries where this product is sold or might be sold. For this purpose, Member States and EEA countries are required to use the RAPEX system under the provisions of the GPSD.

Bilateral

If a product is sold in only one other (neighbouring) country or in a country that is not licensed to use the RAPEX system, Member States should inform each other bilaterally. The aim of this cooperation is to ban the dangerous or unsafe product from the market as soon as possible.

A.1.1.2 Cooperation in case of no safety related non-conformities (reactive)

ICSMS

If a product is detected on the local market that is not immediately dangerous or unsafe but does not comply with all the aspects of the legislation, action must be taken to have the producer or importer correct the product or the attached user manual or safety descriptions. In those cases, market surveillance authorities should inform each other bilaterally (by letter, e-mail or phone), or use the ICSMS system (see H.2.3).

A.1.1.3 Cooperation in surveillance programmes (proactive)

Beside the reactive activities which take place after an unsafe product is detected, Member States can cooperate in surveillance programmes with the aim to check a specific group of products or to search for unsafe products. Because of the large diversity of consumer products and the large number of worldwide producers, market surveillance authorities should tune their programmes with each other to achieve the right spread across the range of products and producers to avoid inefficiency and waste of money.

A.1.1.4 Neighbouring cooperation

'Neighbouring cooperation' has been established by the Baltic Sea Initiative to adjust their import controls and is a good example of neighbouring cooperation in market surveillance. The agreement between Malta and the Netherlands where samples collected by the Maltese authority are tested in the Netherlands, is another example. Similar neighbouring programmes exist in Europe, i.e. Latvia and Lithuania, Poland and the Czech Republic.

A.1.1.5 Joint Actions

More formal and structural cooperation takes place in the 'Joint Actions', funded by the European Commission (DG Sanco) under the framework of the GPSD. Under this programme, each Member State has the possibility to take the initiative to propose subjects for such Joint

Action which aim to promote and support cross-border market surveillance activities. Joint surveillance actions can be undertaken without co-financing from the Commission. Examples of such actions are those for soothers and soother holders, and luminaires.

A.1.1.6 PROSAFE Annual Plans collection programme

PROSAFE recently started the collection of all the annual plans of the Member States and connected countries, with the aim to set up an inventory of such plans and discuss the overview in the PROSAFE meetings and workshops. In the planning stage of their programmes countries should be transparent to their colleagues and make contributions to an Annual Plan Adjusting Programme that PROSAFE is developing.

A.1.1.7 Cooperation in development and improvement

Non-food consumer products are globally traded goods and in most cases produced, distributed or sold by many different companies. Those companies very often work in different countries in parallel and therefore have contact with several market surveillance authorities.

Because of the free market policy on the one hand and the professional image of market surveillance authorities on the other hand, interpretation of test results or risk estimations have to be consistent. Therefore, market surveillance authorities should cooperate in the development and use of risk assessment instruments (e.g. the RAPEX risk assessment model).

The Rapid Advice Forum of PROSAFE has been established to enable market surveillance authorities to consult experts from other countries to check their own opinion and outcomes of their risk assessment process. This should be made use of whenever a potentially hazardous product is identified or a potential new risk has been found.

A.1.1.8 Worldwide networks

Every year, market surveillance authorities from Europe, united in PROSAFE, meet colleagues from USA and Canada (ICPSC / ICPHSO). Guided by a common agenda, they share information and developments in production, products, politics etc. related to market surveillance.

A.1.1.9 Exchange of experts

The exchange of market surveillance officers is the latest form of cooperation. By sending people to other countries to help and to learn, market surveillance authorities work not only on the improvement of the procedures and structures, but also on the motivation and expertise of their officers. The European Commission (DG Sanco) stimulates the exchange of experts with coordination and funding.

A.2 The Cigarette-lighters Project

This annex will present an overview of the joint action for lighters as well as the best practices that will be or have been applied in the action.

A.2.1 Joint action on cigarette lighters – an overview

The action was proposed according to the 'Procedure for the awarding of financial contributions to specific joint surveillance and enforcement actions in the area of consumer product safety (non-food)' and is entitled 'Joint market surveillance Action on Child-Resistant Lighters and Novelty Lighters.'

The objectives of the project are to ensure that lighters placed on the EU market are safe and to gather experience related to best practice techniques with running a joint market surveillance action. The action marks a continuation of the activities that have taken place since 2005 in the so-called Working Group for lighters; a group that includes representatives from the Commission and the Member States as well as stakeholders (industry and consumer representatives).

The action is planned to run from September 2007 to December 2009 and involves 13 Member State authorities in the financial scheme plus a number of authorities outside the financial scheme. It will comprise safety tests of some 150 lighter models plus tests of the child-resistance of another four. The application was sent in by PROSAFE and the action will be coordinated by PROSAFE. The involvement of the Member States is foreseen to be around 2,000 working days. The activities in the Member States will comprise market surveillance authorities as well as customs authorities.

The progress in the project will be monitored in four indicators:

- The share of non-compliant lighters that are found on the European market.
- The share of non-compliant lighters that are imported to Europe.
- The share of non-compliant lighters that are produced in Europe.
- The share of shops that market novelty lighters.

The ambition of the project is to achieve a level below 2% for each indicator at the end of the project.

Regular contacts with industry and consumer organisations are foreseen. They might be scheduled via open parts of the project group meetings or via a continuation of the core group for lighters. Their meetings will be combined with project group meetings.

A.2.2 Best practice techniques applied in the action

Although the action is still ongoing, a number of best practices have already been applied in the project, including the following 6:

1. The action has common, ambitious objectives
From the start, four objectives were defined to 'shape' the ambition in the action. The objectives were ambitious, e.g. 'More than 98% of the lighters on the market in 2008 should comply with the safety requirement'.

The advantage of setting up such objectives was that they helped define the project and the activities, e.g. the necessary number of samples to be taken.

When finalising the application, the participants however found that it would be premature to state the objective too firmly. Therefore, the objectives were changed a bit; the indicators were kept, i.e. the number of lighters that comply with the decision is still traced but it is no longer an objective to reach a level of 98%. It is rather the 'ambition' of the action to achieve such a level.

2. Coordinated sampling plans
The project uses a coordinated sampling plan with common criteria for sampling for all participants. This means that the share of consignments that should be checked is the same in all Member States, the visits to the importers are coordinated at European level and the inspections in the entry points as well.

Furthermore, there will be an exchange of identification on sampled products. The idea is to coordinate the testing and to find out if it is also possible to exchange test results and use them in the follow-up in the different Member States.

It has turned out that those two issues encounter legal obstacles. Some Member States are obliged to observe very strict confidentiality, meaning that information on products under investigation can not be disclosed. Other Member States can only use test results of their own if a case ends up in court. Both questions will be explored further in the project.

3. Involvement of industry
The Commission has involved industry and consumer representatives from the beginning of the activities. The project foresees to continue this involvement as industry has the knowledge of the product, the market, the pitfalls, the risks etc.

It is of course an issue when to involve industry and when not to, because industry will have a different perspective to the activities than Member States, and Member States might want to have introductory discussions of various topics without the involvement of industry. This balance has however been maintained quite well in the working group for lighters.

4. The coordination function
The coordination in itself also seems to represent a step forward in European cooperation as it has meant that common procedures and tools have been developed to a much larger extent than in most other joint actions. In this way the action truly utilises the fact that lighters are produced overseas, are imported by rather few big European importers, and sold Europe-wide.

The tools developed include inventories with pictures that for instance are intended to help Member State authorities decide whether a given lighter design is a novelty lighter or not.

The coordination is also more comprehensive as it includes cooperation between market surveillance authorities and customs in more Member States, the European Commission and industry representatives.

The main challenge in this coordination is to find the balance between one coordinated approach and the procedures in the individual Member States; differences that are caused by tradition and differences in legislation.

5. The Rapid Advice Forum
The participating Member States have come across a lot of problems where the Rapid Advice Forum has proven useful and the procedures of the forum have been developed further to suit the needs of the joint action.

The main topic for discussion among Member States is which lighter designs are to be recognised as novelty lighters. Usually, the problem arises because a Member State authority comes across a new lighter design that is not in the inventory of novelty lighters. What happens now is that the market surveillance officers take a digital photo, attaches it to a mail and sends it to the other colleagues in the project group. They state their opinion (novelty or not novelty) in a few days which means that the officer can continue his procedures knowing the assessment of his colleagues.

Afterwards, the coordinator will enter the new design in the inventory of novelty lighters. The inventory will end up in the public part of the web site set up within the framework of EMARS project (http://prosafe.project.webexworkspace.com/) once it is approved by the participants in the joint action.

6. Joint testing
It has also been decided to do the testing jointly in the action. Therefore, a call for tender was issued to a number of European laboratories and two laboratories have been selected.

The coordination of the testing is presently done in such a way that a number of deadlines have been set over the course of the project when lighters must be submitted to the laboratory. In this way, Member States know beforehand when to have samples ready for testing.

The test reports are uploaded to a database that is established on the Webex system to allow all participants to make use of them.

A.3 The LVD-ADCO Projects (Luminaires and extension cords)

A.3.1 Cross-border market surveillance actions in the area of the Low Voltage Directive

In reaction to a growing realisation that cross-border cooperation in market surveillance of the LVD is becoming more and more a necessity, LVD AdCo initiated a first cross-border market surveillance action, to be performed in 2006.

The purposes of this action were:
- To gain experiences with cross-border market surveillance;
- to exchange information on market surveillance practices in the Member States in the area of the LVD;
- to collect information on the differences and similarities between the participating Member States with respect to the effects of differences in their market surveillance practice;
- identify obstacles that hinder cross-border market surveillance; and
- to raise the profile of market surveillance in the field of the LVD in the minds of consumer organisations and industry.

Within the context of this specific project the secondary goal was law enforcement in the cross-border setting.

A.3.1.1 Cross-border action luminaires – overview

Point of departure in designing the action was the desire to involve as many Member States as possible. To make participation as easy as possible:
- Member States were explicitly allowed to organise and manage their share in the action according to the procedures applicable for their organisation.
- Coordination and support was provided where needed.
- The action was designed such that Member States with only moderate means and infrastructure at their disposal could also participate. Thus the subject of the action was the category luminaires, for which a purposeful action could be designed using simple and inexpensive tests.

Coordination
The responsibility for the design and coordination of the cross-border action on luminaires was assigned to one of the Member States by LVD-AdCo, to be supported by a task force consisting of representatives of a number of the participating Member States. Besides assuring representation of the participants in the design and management of the action, the task force agreed to back up and help the project coordinator in refining the project description and development of the test programme, sampling requirements, organisation of information exchange, and compiling a practical project guide for inspectors and laboratories and a question and answer sheet. In addition, the task force was required to support the project coordinator in the practical coordination required during the execution of the project.

Participation
Market surveillance authorities of 15 Member States participated in the luminaire cross-border action. Two participants depended on other participants for testing; three of the participants were willing to assist in the measurements for these participants. Five of the 15 participants belonged to the so-called 'New Member States' and two were EFTA partners.

A.3.2 Best practice techniques applied in this action

Best practices were not an important concern in this first LVD cross-border action, though the design of the action incorporated several aspects that can be considered best practices such as the following seven examples:

1. Risk based selection of luminaires as the subject for the cross-border action
Although the primary objective was to select a product group which could be inspected and tested simply and inexpensively, the risk presented by the product group was the most important secondary consideration. Luminaires were chosen for the following reasons:
- Luminaires are the subject of many RAPEX notifications in the LVD field. Also luminaires often figure in safeguard clause procedures under Article 9 of the LVD.
- Previous experiences in several Member States indicated high levels of non-compliance.
- Non-compliances reported in RAPEX notifications and by Member States frequently concern serious safety shortcomings, possibly leading to risk of electric shock and fire hazards.
- Accident and fire statistics were studied, but regrettably no clear data linking these hazards to luminaires could be identified.

2. Clear definition of the scope of the project
The scope of the action was limited to a subset of the luminaires standardised in EN 60598. Restricting the scope to a subset of this standard avoids a multitude of test programmes for different varieties of luminaires. Excluded were for example luminaires with fluorescent tubes and low-voltage luminaires with transformers.

Restriction of the scope allowed a standard testing programme for all samples which is more cost-effective per sample.

In order to facilitate the field officers to select the proper samples clear instructions on what to sample were issued, including instruction on how to administrate and evaluate administrative shortcomings.

3. Risk-based definition of the test programme
Compliance was tested against a restricted set of requirements from EN 60598. The requirements to be tested were selected on the base of the risks they addressed, so that all tests performed had direct bearing on the safety. Hazards addressed included the risk of electric shock, fire hazard and mechanical risks of injury. In effect, the tests performed comprised amongst others requirements for cord anchorage, earthing, cross-diameter conductors and insulation.

4. Selection of businesses for inspection and sampling
Inspections were to be aimed at EU importers and manufacturers and Member States were asked to take sales volumes into account. For that purpose a preliminary market analysis was scheduled in which the participating authorities were asked to identify the importers and manufacturers of luminaires and estimate their relative sales volumes. Inspections and sampling were requested to be performed proportional to sales volumes on the premise that cleaning up large volumes contributes more to consumer safety than measures against luminaires that hardly sell. Since the action was planned as enforcement, inspectors were instructed to select samples suspected of non-compliances.

5. Checklists and guide on how to sample and evaluate the conformity of samples
To assure uniformity of sampling with the project scope, of laboratory testing and of compliance evaluation guides for the field inspectors and laboratories were made available, describing what and how to sample; how to perform laboratory testing and how to evaluate the conformity of samples. Electronic data-entry sheets, functioning as checklist were also made available.

6. Information exchange
A mechanism for the exchange of information was set up using the CIRCA system. The system was meant to assure the timely exchange of information about samples and businesses inspected by the participants, in order to avoid double sampling and testing of identical luminaires, as well as a means for collecting the results of the action for reporting purposes. The system used provided for unique codification of the samples taken and was to make available pictures of the samples taken to the field inspectors.

7. Uniform codification of shortcomings
To assure uniform evaluation of the shortcomings found use was made of the Nordic Failure Code List. The list classifies specific shortcomings frequently found in electrical equipment in three categories of increasing severity (F1, F2, F3).

A.3.2.1 Summary of results of the cross-border action on luminaires

In the luminaires action the compliance of 226 luminaires against the administrative requirements of the LVD and against a number of requirements from the applicable standard were checked. Only 11 of the investigated luminaires showed no shortcomings at all. Products with only administrative shortcomings (CE-marking, DOC and TCF) were found 53 times, while 162 luminaires showed technical shortcomings.

More detailed results can be found in the final report on the luminaires action: http://ec.europa.eu/consumers/safety/projects/docs/report_international_cord_extension_en.pdf.

This report also discusses extensively the difficulties encountered in applying some of the practices requested in the project:

- The working methods and/or organisation of some participants did not always allow premarket orientation. Some Member States also reported that they do not usually sample at importers/producers.
- The information exchange mechanism did not function as intended which meant that inspections and sampling generally took place without awareness of what other authorities had already done.
- Although use of the Nordic Failure Code List indeed resulted in largely coherent classification of the shortcomings found during the action, agreement on classification did not always extend to the resulting legal measures taken. One reason is that legal follow-up after a specific shortcoming has been codified in the quality manuals used by the market surveillance authority in several Member States.

A.3.3 Joint action on multiple outlet cord extension sets – overview.

Grant under the joint action programme

The luminaire action was followed by a cross-border action on multiple outlet extension cords which took place during 2007. This cross-border action on extension cords

was partly financed by the European Commission under the joint action programme. The project application for the extension cord project was formally submitted by the Netherlands and included 15 participating Member States that applied for financial support from the Commission. Participating without being partner in the grant agreement for the action were five Member States/EFTA countries, bringing the total number of participants to 20.

Organisation and coordination
The general organisation and setup of this cross-border action closely resembled that of the luminaires action. Coordination and management were the responsibility of one of the Member States (Austria), supported by a task force consisting of seven representatives of the participants. Information exchange and data collection used the same CIRCA based system previously developed for the luminaire action.

Project design and development were largely comparable with the design and development of the luminaire project, except for increased complexity of this project and a few important differences in approach:

- Because there are four different system for plugs and sockets in use within the European union, each with corresponding national standards, comparable safety shortcomings in all the systems had to report and had to be coupled to comparable requirements in the standards for the different systems.
- The action aimed at obtaining a reliable estimate of the compliance levels in the market by prescribing quasi-random sampling.
- Instead of a restricted set of requirements, the action prescribed an almost complete conformity assessment, testing many of the standard requirements (22 test parameters).

The other best practices used in the luminaire action were also applied in the extension cord action, including risk-based selection of extension cords as the subject of the action, definition of a clear scope of the action, use of the Nordic Failure Code List and instruction on how to sample and collect and exchange data via the Circa system.

A.3.3.1 Summary of results of the cross-border action on extension cords

In the extension cords action a total of 209 extension cords were investigated by 20 participants. Since this action aimed to obtain reliable estimates of the observance levels, the results may be taken as indicative of the compliance levels of products in this market.

From the results it appears that a large proportion of the companies active in this market do not comply with the administrative requirements: for 74% of the samples tested CE-marking (13%), Declaration of Conformity (54%) or technical file (74%) were lacking.

The most frequent technical deficiencies were wrong shape and dimensions of plugs and sockets (43%), poor construction of the cord – i.e. inadequate insulation material (26%), and insufficient protection against electric shock (21%). Less frequent technical shortcomings were dielectric strength and material properties (resistance to ageing, temperature and fire) which did not meet the requirements in less than 10% of the cases. The report on the extension cord action can be found at CIRCA:

http://circa.europa.eu/Members/irc/enterprise/esg/library?l=/meetings_workshops/adco_meetings/administrative_2008-03-0/08-04doc_atpdfpdf/_EN_1.0_&a=d.

The clear conclusion drawn from this action was that compliance levels of extension cords are disappointingly low, leading to the recommendation to repeat the action in due time in a slightly trimmed form.

A.3.4 Cross-border market surveillance in the LVD area – ongoing developments

The cross-border market surveillance actions on luminaires and extension cords have produced a wealth of experiences about the organisation and running of cross-border reactions which LVD-AdCo intends to capitalise upon. The actions revealed a number of bottlenecks and obstacles which hinder the development of multinational market surveillance in the area of the LVD, but also showed that cross-border actions can be organised successfully. To further develop cross-border market surveillance in the area of the LVD several recommendations to LVD AdCo were extracted from the experiences:

- LVD AdCo was recommended to organise cross-border market surveillance campaigns regularly, at least once a year;
- LVD ADCO was recommended to stimulate small-scale co-operation between interested Member States by collecting the annual activity plans of its members, making them available to its members and encourage bi- or multilateral local co-operation;
- LVD ADCO was advised to set up a working group in order to investigate the possibilities for harmonizing the relation between the risk classification of common shortcomings found in electrical products under the LVD and the interventions the authorities decide upon; and
- LVD ADCO was recommended to investigate the requirements for an improved information exchange system to facilitate cross-border actions.

Currently LVD ADCO has acted on all these recommendations. Small working groups address the harmonisation of the relation between specific non-compliances and interventions and the need for better information exchange. New cross-border actions are scheduled (i.e. for lighting chains and sun beds) and the possibilities for small-scale cooperation are investigated in cooperation with the EMARS initiatives in that area.

A.4 The Playground equipment Project

The Polish authority OCCP (office of competition and consumer products) operates this project. The project start-up meeting was held in Warsaw in October 2007. The main objectives are to develop guidelines for economical operators and users of playground equipment. EMARS WP 3 is cooperating with the project in order to achieve feedback related to the Book. In the project start-up meeting the ideas of cooperation were presented. This will be followed up by a closer coordination with Chapters 4 to 7 in the Book.

The joint project 'safe play in the playground', initiated by the Polish OCCP (office for competition and consumer product), started in autumn 2007. This project was funded by the Commission under GPSD art. 10, and involves eight countries.

The deliverables of this project are twofold:

1. Inspectors' handbook for inspection of playgrounds.
2. Information to parents, operators and producers of safety of playground equipment by means of leaflets and brochures.

The playground handbook is based on the Belgian guide for inspection of playgrounds. This part of the handbook deals with technical aspects related to playground equipment.

The different stages of inspection programmes in playgrounds have links to this Book on best practice techniques. Chapters 6 to 9 of this Book, dealing with the planning stage, implementation, reporting, analyzing and information have been used as guide for writing the different chapters in the playground handbook and resulted in a practical approach for the performance of actions.

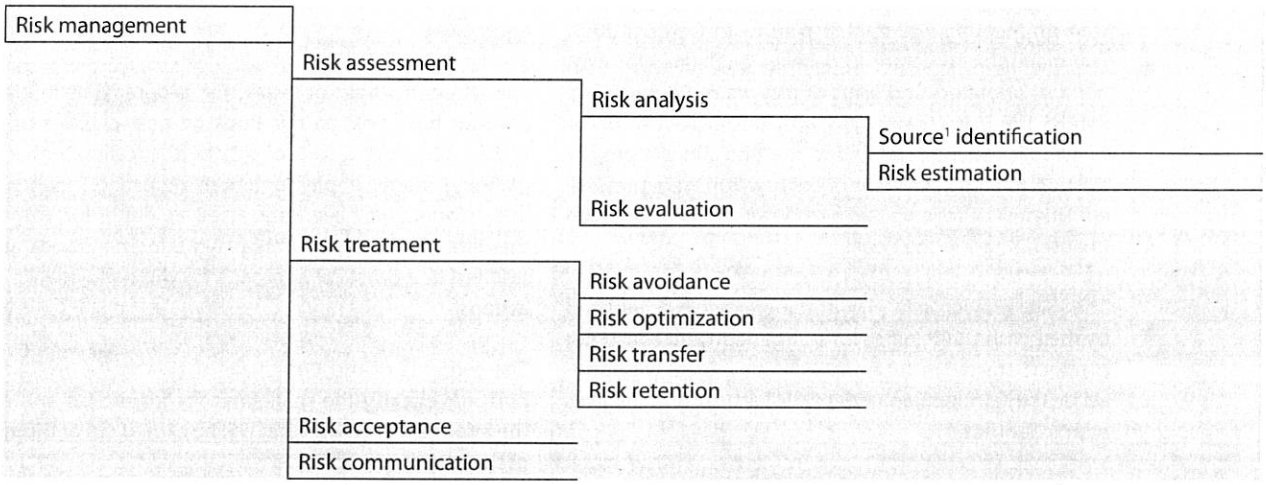
The contents of this Book have shown to be useful for both developing the guidelines for inspection and for the information actions that will be carried out at the end of the project.

ANNEX B – DIFFERENT FRAMEWORKS OF RISK ASSESSMENT

It may be confusing that at least two different risk assessment frameworks are used, each with its own definitions. One is common in engineering and accident prevention, in particular the framework adopted by ISO for the safety of machines (ISO 12100) and for product safety in general. Another is used for food and feed safety (adopted by the WHO and FAO), and for chemical safety (WHO IPCS, TGD). As RAPEX notifications may involve both physical hazards and chemical substances, market surveillance authorities may encounter both frameworks. In this annex, we briefly explain the differences between these two frameworks.

Schemes of the risk assessment process

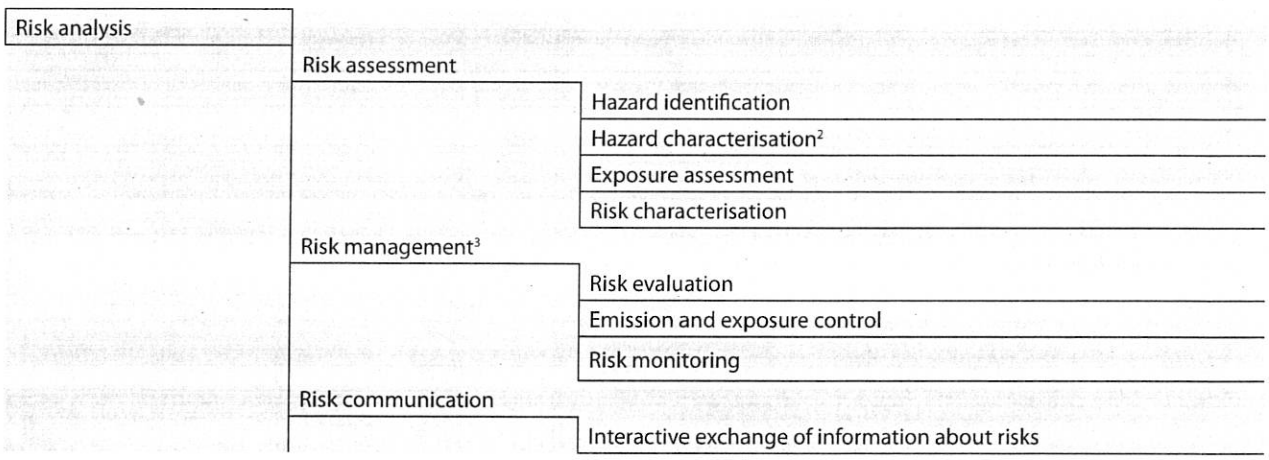
A. ISO 12100, ISO/IEC Guide 51 and ISO Guide 73



[1] In Guide 51, the term 'hazard' is used, defined as a potential source of harm.

The most general term here is 'Risk management' which consists of the elements 'Risk assessment', 'Risk treatment', 'Risk acceptance' and 'Risk communication'. Within 'Risk assessment' in turn two steps are distinguished: 'Risk analysis' and 'Risk evaluation' etc.

B. IPCS Risk assessment Terminology, Key Generic Terms used in Chemical Hazard/Risk Assessment; WHO/FAO framework for risk analysis in food; EU Technical Guidance document on Risk Assessment (TGD)



[2] Includes dose-response assessment; TGD uses 'effects assessment' as an overall term for hazard identification and dose-response assessment.

[3] WHO/FAO have four components here: preliminary risk management activities; evaluation of risk management options; implementation of risk management decision; monitoring and review.

Here, the general term is 'Risk analysis' consisting of the activities 'Risk assessment', 'Risk management' and 'Risk communication' etc.

Due to the different ways of dividing the process, it is not possible to simply make a correlation table to translate terms. For example, the ISO/IEC term *risk estimation*

is more or less a combination of *hazard characterisation* and *exposure assessment. Risk evaluation* in the ISO/IEC framework can be compared with *risk characterisation* combined with *risk evaluation* in the IPCS terminology.

The following definitions are used in the IPCS document:

Risk
The probability of an adverse effect in an organism caused under specified circumstances by exposure to an agent.

Agent
A chemical substance which may cause adverse effects such as injury or damage to health.
NOTE: In this definition, we extend the meaning of 'agent' from chemical substance to include physical hazards.

Risk assessment
A process intended to calculate or estimate the risk to a given target organism, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target organism.

The risk assessment process includes four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Hazard identification
The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system or (sub)population.

NOTE: The result of this step should be a number of scenarios that may occur including the health outcomes (endpoints).

Hazard characterisation
The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

NOTE: The result of this step should be a justified conclusion about the severity of the adverse effects. The tool used for this in the RAPEX Guidelines is the injury table.

Exposure assessment
Evaluation of the exposure of an organism, system or (sub)population to an agent.

NOTE: General relevant parameters are frequency of contact with the product, exposure pathways and behaviour of person and vulnerability of person.

For chemical substances, exposure is usually expressed as mg substance per kg body weight that is taken up by inhalation, dermal contact or ingestion; specific parameters include evaporation or diffusion.

For physical hazards, relevant parameters can be the probability that a scenario will occur, energy transferred to a body part etc.

Risk characterisation
The qualitative and, wherever possible, quantitative determination, including attendant uncertainties of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions.

NOTE: The result of this phase is a conclusion on the expected risk level in terms of severity and probability. It may include a quantitative probability distribution of adverse effects and confidence intervals or sensitivity analysis.

ANNEX C – RISK ASSESSMENT EXAMPLES

C.1 Hammer (case taken from RAPEX notification number 0125/06)

C.1.1 Identification of product and case, description of the context

This case deals with a cross pane hammer with metal handle and black plastic grip. The hammer head is insufficiently fastened to the handle and the plastic grip breaks under normal strain.

C.1.2 Description of the hazards

The hammer has three dangerous shortcomings:

1. The hammer head is insufficiently fastened to the handle.
2. The plastic grip breaks under normal strain.
3. The hammer head is made of brittle material with insufficient dynamic impact strength.

All hazards may result in parts breaking off hitting the user or a bystander.

Table 7: Table of injury scenarios and associated risk levels for the hammer case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Part flies into eye.	Foreign body in eye, blindness in 1 eye	3	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting head: 1/3 (p = 0.33) • Hitting eye: 1/20 (p = 0.05)	1/6,000 (p = 0.0001667)	High risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Large part hits head.	Fracture of nose or teeth, contusions	1	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting head: 1/3 (p = 0.33)	1/300 (p = 0.0033)	Low risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Large part hits hand, foot or other body part.	Contusion of hand, finger etc.	1	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting body parts: 2/3 (p = 0.66)	1/150 (p = 0.0066)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).	Concussion < 1 hour	2	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01) • Hitting head: 1/10 (p = 0.1)	1/50,000 (p = 0.00002)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).	Broken nose or teeth	1	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01) • Hitting head: 1/10 (p = 0.1)	1/50,000 (p = 0.00002)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits body part of user or other person.	Contusion of hand, finger etc.	1	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01)	1/5,000 (p = 0.0002)	Low risk
Defect: grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Contusion of arm	1	• Handle breaking: 1/2 (p = 0.5) • Hitting arm: 1/5 (p = 0.2)	1/10 (p = 0.1)	Significant risk

C.1.3 Description of injury scenarios and probability

A sensitivity analysis has not been carried out. However, the probability of the first injury scenario (which has the highest risk level) can be a factor of 6 higher before the risk changes to 'serious risk'. All other scenarios will not reach the 'serious risk' level with reasonable assumptions for the probability.

C.1.4 Conclusion

The result of this analysis is that one scenario has the outcome 'high risk' (which happens to be the most serious outcome). Five scenarios result in 'low risk' and the last one ends in 'significant risk'.

The overall outcome of the analysis it that the risk is high, i.e. action against the product should be taken, but there is no need for a rapid intervention and RAPEX notifications.

C.2 Rubber luggage straps (assessment initialised by an accident)

C.2.1 Identification of product and case, description of the context

This case deals with a rubber luggage strap with metal hooks on both ends. The strap is used for tying luggage to bicycles, motorcycles or to the roof of a car.
The case is provided by VWA in the Netherlands. In the Netherlands some 30 accidents are reported each year. Half of them result in eye injuries of which 50% result in permanent injury. There are even a few cases of lost eyes and blindness on one eye.

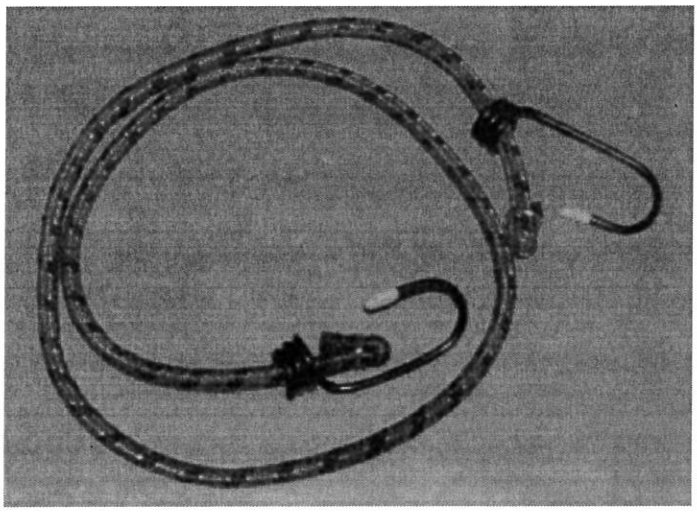


Figure 27: Rubber strap used for tying luggage to motorcycles or cars.

C.2.2 Description of the hazards

The hooks at both ends of the strap are of poor quality: the hooks bend open if the tension exceeds a certain level resulting in hitting the user with high force. The most severe injury will occur if the hook at the opposite end of the strap bends open.

(Outside the scope of this scenario: a number of accidents happen when the user attaches the hooks poorly, so that the hook comes loose while tightening the strap.)

C.2.3 Description of injury scenarios and probability

One injury scenario has been developed based on a case found in an article in a medical journal.

The estimate of the probability that a hook at the end of a strap will open carries the highest uncertainty in the calculation. If the resulting probability increases to 1/10,000 (a factor of 6) then the risk level increases to 'high risk'.

C.2.4 Conclusion

The result of the analysis is that the risk level is 'significant risk'.

A special problem arises because the probability of an accident might be low but the number of products is high. In the actual case, a low probability is 'multiplied' by a serious consequence and the result is a low risk. Still the fact is that the big number of products implies that there are quite a few injuries every year. These should be taken into account when deciding on the appropriate risk management measures.

Table 8: Most severe injury scenario and associated risk level for the rubber strap case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Person tries to fix luggage while standing in the line of the strap; hook on other end opens and hits person in the eye.	Permanent low vision in one eye	3	Person standing in line: 1/2 (p = 0.5) Hook opening: 1/100 (p = 0.01) Hitting head: 1/3 (p = 0.33) Hitting eye: 1/20 (p = 0.05) Eye injury: 1/5 (p = 0.2)	1/60,000 (p = 0.0000165)	Significant risk

C.3 Socket protectors

C.3.1 Identification of product and case, description of the context

This case deals with socket protectors – devices that users (parents) put on the electrical socket outlets. The

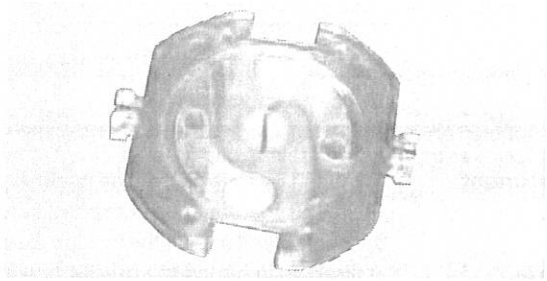


Figure 28: Socket protector that prevents children from sticking pointy things into power outlets.

socket protectors should ensure that small children can not get an electric shock (possibly fatal) by accessing live parts by introducing long metal objects into the power outlet.

C.3.2 Description of the hazards

The holes in this protector (where the pins of the plug go through) are so narrow that the pins might get stuck.

C.3.3 Description of injury scenarios and probability

There is the risk that the user will pull the protector of the outlet when the plug is pulled out. If the user does not notice this happening (or does not replace the protector), the outlet is not secured. Therefore, the product will not provide the protection that the parents rely on.

The outcomes of the analyses were one scenario resulting in 'serious risk' and one in 'low risk'. The calculations are based on an estimated probability that the protector can be removed unintendedly over the lifetime of the product of 90%. A sensitivity analysis revealed that only if this probability is less than 0.1%, the outcome would change to 'significant risk'.

Some homes have residual current breakers that will interrupt the power if a person touches the live wire. This is included in the analyses as an extra factor in the calculation of the probability in the three scenarios. It does not affect the outcome.

For comparison, we have made an analysis for an unprotected socket outlet. In this case, the parent does not expect protection and therefore it seems less likely that the child will be left unattended near the outlet.

Table 9: Table of injury scenarios and associated risk levels for the socket protector case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Protector is removed from the plug which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.	Electrocution	4	• removing of protector 9/10 (p = 0.9) • not noticing the removal of protector 1/10 (p = 0.1) • child is playing with thin conductible object 1/10 (p = 0.1) • child is unattended when playing 1/2 (p = 0.5) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • electrocution due to voltage (without circuit interrupter) 1/4 (p = 0.25)	27/160,000 (> 1/10,000 (p = 0.00017)	Serious risk
Protector is removed from the plug which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and sustains shock.	Burns 2nd degree	1	• removing of protector 9/10 (p = 0.9) • not noticing the removal of protector 1/10 (p = 0.1) • child is playing with thin conductible object 1/10 (p = 0.1) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • child is unattended when playing 1/2 (p = 0.5) • burn due to voltage (without circuit interrupter) 3/4 (p = 0.75)	81/160,000 (> 1/10,000) (p = 0.0005)	Low risk

Table 10: The injury scenario and associated risk level for an unprotected socket outlet.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Socket unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.	Electrocution	4	• child is playing with thin conductible object 1/10 (p = 0.1) • child is unattended when playing 1/100 (p = 0.01) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • electrocution due to voltage (without circuit interrupter) 1/4 (p = 0.25)	3/80,000 (> 1/100,000) (p = 0.0000375)	High risk

C.3.4 Conclusion

The product in itself is not dangerous. The risk arises because the product tempts the users to change their habits because they rely on the protective properties of the product.

The overall outcome of the analysis it that the risk is serious, i.e. rapid action against the product should be taken.

C.4 Bathing mattresses

C.4.1 Identification of product and case, description of the context

This case deals with a type of bathing mattress, an inflatable airbed for seaside and pools made from PVC.

C.4.2 Description of the hazards

The PVC contains a plasticiser: a substance to make the plastic flexible. In this case, the substance is bis(2 ethylhexyl)phthalate (DEHP). DEHP and other phthalates are classified in Annex I to Directive 67/548/EEC as a dangerous substance because of reproductive toxicity – Category 2 'Suspected human reproductive toxicant'; the packaging of this substance needs to carry the warning sentences R60-61 'R60: May impair fertility' and 'R61: May cause harm to the unborn child'.

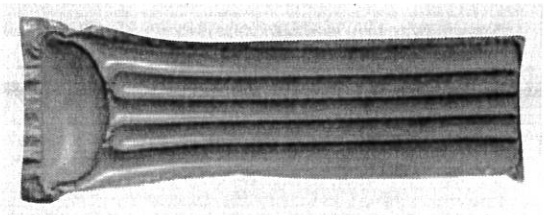


Figure 29: Bathing mattress that emits phthalates.

C.4.3 Description of injury scenarios and probability

In order to assess the risk of this particular product, we need to know if DEHP can migrate out of the plastic and how much human exposure would take place. The first part of such a risk assessment is similar to the physical examples: describing one or more scenarios. After that, the probability is dealt with in a different way. We do not estimate how probable the scenario is, but how much of the substance the person is likely to get into his body. This can be done using (measured or estimated) data on release, transfer and absorption.

Table 11: Table of injury scenarios and associated risk levels for the bathing mattress case.

Injury scenarios	Injury type and location	Severity of injuries	Exposure parameters (Probability of injuries)	Resulting exposure (probability)	Risk
Use by a 5 year old boy. The DEHP present in the air mattress is released from the surface.	Effects on reproduction	4	• Body weight: 16 kg • Release of DEHP: 7.4 µg/cm²/h	104.6 µg/kg_{BW}/day	Margin of safety insufficient, serious risk
The released amount of DEHP is transferred to the skin via direct physical contact and rubbing with the skin.			• Transfer to skin: all released DEHP gets on an area of skin of 1500 cm², during 2 h per day		
The transferred amount of DEHP to the skin is absorbed.			• Absorption of DEHP: 5%		

The risk in chemical cases can not directly be derived from the risk table, because there is no probability class such as '>1/100.000'. Instead, we have a dose which is usually expressed in an amount per kg of body weight.

We then compare this dose with data on the levels that have been reported to produce the effect we mentioned under 'injury type'.

In this case, there are data on the highest tested level that did not produce the effect in rats: 4800 $\mu g/kg_{BW}$/day. Higher doses did give the effect of developmental toxicity. Toxicologists then say that the *No Observed Adverse Effect Level* (NOAEL) is 4800 $\mu g/kg_{BW}$/day.

The ratio between the NOAEL and the value calculated for the mattress is 4800/104.6 = 45.8. This ratio is called the Margin of Safety. A Margin of Safety of 45.8 is considered insufficient by toxicologists. It should be more than 100, because we need to take into account the differences in metabolism between rats and humans as well as between different persons (inter- and intra-species variability).

C.4.4 Conclusion

The Margin of Safety is not sufficient; therefore, the product poses a risk. Because the effect that may occur is in the highest category and the margin of safety is well below 100, we consider this a serious risk.

C.5 Toy with small parts

C.5.1 Identification of product and case, description of the context

This case deals with a push-along toy that was notified by Belgium in 2008 (RAPEX notification 0265/08).

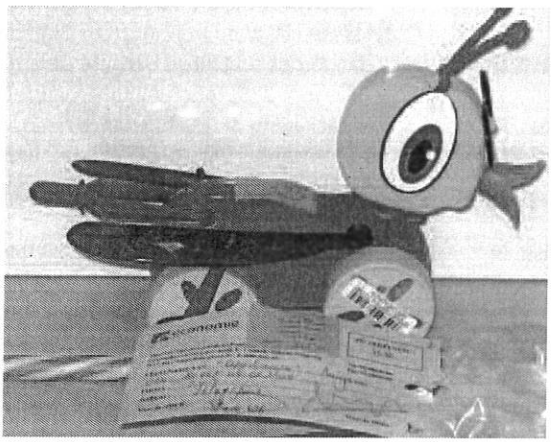


Figure 30: A toy with detachable small parts.

C.5.2 Description of the hazards

According to the RAPEX notification the toy poses a serious risk of choking because the duck's beak can be detached at a force of 19 N (the requirement from EN 71-1 is 100 N). The detached part fits into the small parts cylinder.

C.5.3 Description of injury scenarios and probability

The outcome of the analysis is a scenario resulting in 'high risk'. The assumptions behind this calculation are:

- The beak is so poorly attached that it will sooner or later come off (all products in this batch affected);
- The child will be alone while playing with the toy in 50% of the cases when the beak detaches;
- It is considered to be normal behaviour for small children to examine objects by putting them in the mouth;
- It is assumed that the beak is so small that it does not get stuck in the larynx; only if it is aspired, it will cause (partial) blocking of the airways.

The resulting probability 1/2,000 falls in the category '> 1/10,000' but it is close to the category '> 1,000'. A sensitivity analysis revealed that using this category instead will change the outcome to 'serious risk'. Moreover, the severity could increase as well: depending on the shape, size and material of the beak, the part might cause complete blocking of the airways leading to permanent damage or death. Taking the uncertainties into account the result of the risk assessment is changed to 'serious risk'.

C.5.4 Conclusion

The overall outcome of the analysis it that the risk is serious, i.e. rapid action against the product should be taken.

Table 12: Injury scenario and associated risk level for the toy with a detachable small part.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
The child detaches the beak. The parents don't notice or don't react. The child puts the beak in his mouth. The small part goes into the child's airways and surgery is necessary.	Oxygen flows to brain blocked without permanent consequences	3	• Beak is detached 1/1 (p = 1) • Parents don't notice 1/2 (p = 0.5) • Child puts beak in mouth 1/1 (p = 1) • Beak gets in the child's airways 1/1,000 (p = 0.001)	1/2,000 (> 1/10,000) (p = 0.0005)	High risk

C.6 Candle

C.6.1 Identification of product and case, description of the context

Candles containing plant parts, e.g. sunflower seeds or coffee beans, have been reported to burn intensely with high flames. There have been at least two RAPEX recalls for candles in 2006: 0351/06 and 0563/06.

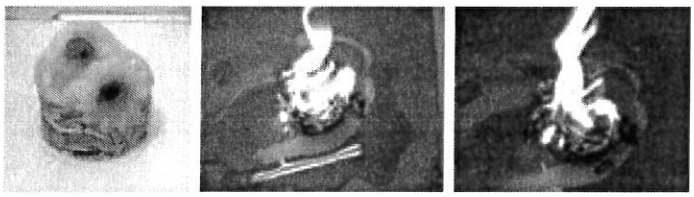


Figure 31: Candles containing plant parts may burn intensely with high flames and cause fires.

C.6.2 Description of the hazards

When the candle burns down melting the wax, the plant parts begin to float in the melted wax. At this stage the plant parts will heat up or get stuck to the wick which may cause the parts to catch fire. This fire will usually evolve rapidly, melt the rest of the candle and might put fire to the furniture where the candle is placed. If nobody is present at this stage this will most likely develop into a fire that can cause harm to people.

Another hazard is small plant parts easily detachable and fitting into the small parts cylinder. This will make them dangerous if small children swallow them.

C.6.3 Description of injury scenarios and probability

Several scenarios for these candles create a serious risk. A sensitivity analysis shows that these serious risk levels remain valid, even if the probability would be a factor 10 lower.

The uncertainty in this case is rather high because several steps in the scenarios depend on behaviour rather than physical parameters.

It is noted that fires often result in considerable damage to property, even when there are no people injured. This risk can not be estimated according to the standard RAPEX table. Instead, we have assumed for this assessment that a certain percentage of house fires leads to fatalities.

C.6.4 Conclusion

The overall outcome of the analysis is that the risk is serious.

Table 13: Table of injury scenarios and associated risk levels for the candle case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Seeds or beans catch fire generating high flames. Person blows out flames and tries to move the candle. Hot wax flows over the hands of person.	Scalds on hands	1	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person tries to move the candle: 1/4. (p = 0.25) • Hot wax flows over the hands: 3/4. (p = 0.75)	27/160 (> 1/10) (p = 0.16875)	Significant risk
Seeds or beans catch fire generating high flames. Person tries to extinguish flames by covering or pouring liquid. Flames reach the hands of person.	Burns on hands	1	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person tries to extinguish flames: 9/10. (p = 0.9) • Flames reach hands: 1/20. (p = 0.05)	81/2000 (> 1/100) (p = 0.0405)	Significant risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are not in room, but inhale toxic fumes.	Fatal poisoning	4	• Seeds or beans catch fire: 9/10. (p = 0.9) • People not in the room for some time: 1/3. (p = 0.33) • Furniture or curtains catch fire: 1/2 (depends on surface on which candle is placed) (p = 0.5) • Persons inhale toxic fumes: 1/20. (p = 0.05)	> 1/1,000 (p = 0.0075)	Serious risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are in room and inhale toxic fumes.	Fatal poisoning	4	• Seeds or beans catch fire: 9/10. (p = 0.9) • Furniture or curtains catch fire: 1/2. (p = 0.5) • Persons are in room (e.g. sleeping): 1/100. (p = 0.01) • Persons inhale toxic fumes: 1/1. (p = 1)	> 1/1,000 (p = 0.045)	Serious risk
Seeds or beans catch fire generating high flames. Person sits close to the candle. Flames ignite hair or clothing of person.	Burns over large part of body, may include the head	3	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person sits close to the candle: 1/1000. (p = 0.001) • Flames ignite hair or clothing of person: 1/1000. (p = 0.001)	< 1/1,000,000 (p = 0.0000009)	Low risk
Seeds or beans are attractive to children. Children pick them out of the candle, put them in mouth and it enters the trachea. Child is suffocated.	Suffocation	4	• Children pick seeds out of the candle: 1/10. (p = 0.1) • Seed put in mouth: 1/10. (p = 0.1) • Seed enters the trachea: 1/100. (p = 0.01) • Child is suffocated: 1/1 (p = 1)	> 1/10,000 (p = 0.0001)	Serious risk

ANNEX D – RISK COMMUNICATION

Risk Communication is recognised as an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties (FAO/WHO, 1997).

There are various reasons why risk communication is important. The European Economic Area (EEA) operates as a single market. Therefore, it is necessary that all its Member States harmonise actions that are taken with regard to dangerous products at national level. The objective of the GPSD and the New Approach Directives was to adopt a single set of rules applicable in all the Member States. Thus, action taken in one Member State to safeguard the health and safety of consumers can very well be adopted by the other Member States. This can only be achieved if there is a good communication infrastructure and network between the members.

Risk Communication is part of the Risk Analysis. Risk Analysis is the philosophy and the fundamental methodology underlying the development of legislation and product standards. It is composed of three separate but integrated elements: Risk Assessment, Risk Management and Risk Communication. Figure 33 introduces the WHO/FAO framework for risk analysis for food but the method may also be adopted in non-food product safety areas.

D.1 Fundamental Concepts

Following a proper 'Risk Assessment' (see Chapter 10) carried out by product safety experts in order to identify the risk level posed by a product, a strategy must be developed to identify the ways to eliminate or reduce the risk to an acceptable level. This is called 'Risk Management'. Managing the risk may consist of various kinds of actions depending on the outcome of the Risk Assessment (please refer to Part C of this Handbook). The final important step is to undertake an effective 'Risk Communication' to communicate the risk in the best possible manner and to reach all those who are exposed to the said risk. In order to control and minimise risks, all these steps have to be in place and interlinked.

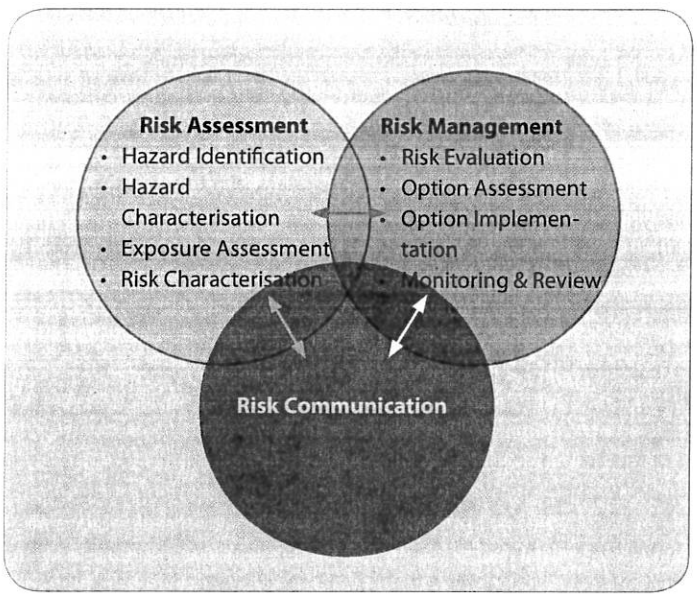


Figure 32: The relationship between Risk Assessment, Risk Management & Risk Communication.

If the outcome of risk assessment is a low risk, authorities still have to impose corrective action but there is no need to implement a full blown information campaign or cause unwarranted alarm, although some information should still be communicated to consumers. Communication should rather consist of oral communication with the respective producers to reduce or eliminate the risk posed by a product.

On the other hand, if the outcome of risk assessment is a high risk, an immediate action has to be taken in order to eliminate the danger to consumers. First, it is necessary to identify who is in danger and to decide on the appropriate method of communication (refer to the following Figure 33):

The first column shows the origin of the risk identified. It is important to establish whether this risk has been identified through local inspections carried out by national market surveillance officers, in the EEA or by other organisations situated in other parts of the world such as the United States Consumer Product Safety Commission.

The second column, the risk identification column, shows the four different levels of risk, ranging from serious risk to low risk. In order to identify the risk level, an expert has to perform a systematic process called 'risk assessment' (refer to Chapter 10). This process should be repeated if the risk assessment process has been carried out by entities outside your territory, e.g. other Member State market surveillance authorities, to identify whether the risk is also applicable in your country. It is extremely important to categorise the risk associated with the product and to assess the exposure to the risk at local level. If the outcome of the risk assessment is high, it is obvious that immediate action has to be taken in order to eliminate or reduce the identified risk to an acceptable level. On the other hand, if the outcome is low, action may not be urgent but still must be taken.

After the risk identification process, it is necessary to assess the tools (column 3) available to communicate the risk with the entities involved (column 4), e.g. consumer segments at risk. A thorough analysis should be carried out in order to choose the best possible tool(s) to reach the target audience and to send them an accurate message. Such communication strategies can only be effective if they are planned carefully. Apart from reaching the target audience in the shortest possible time, choosing the best available tool(s) will also save costs for the authorities and affected businesses.

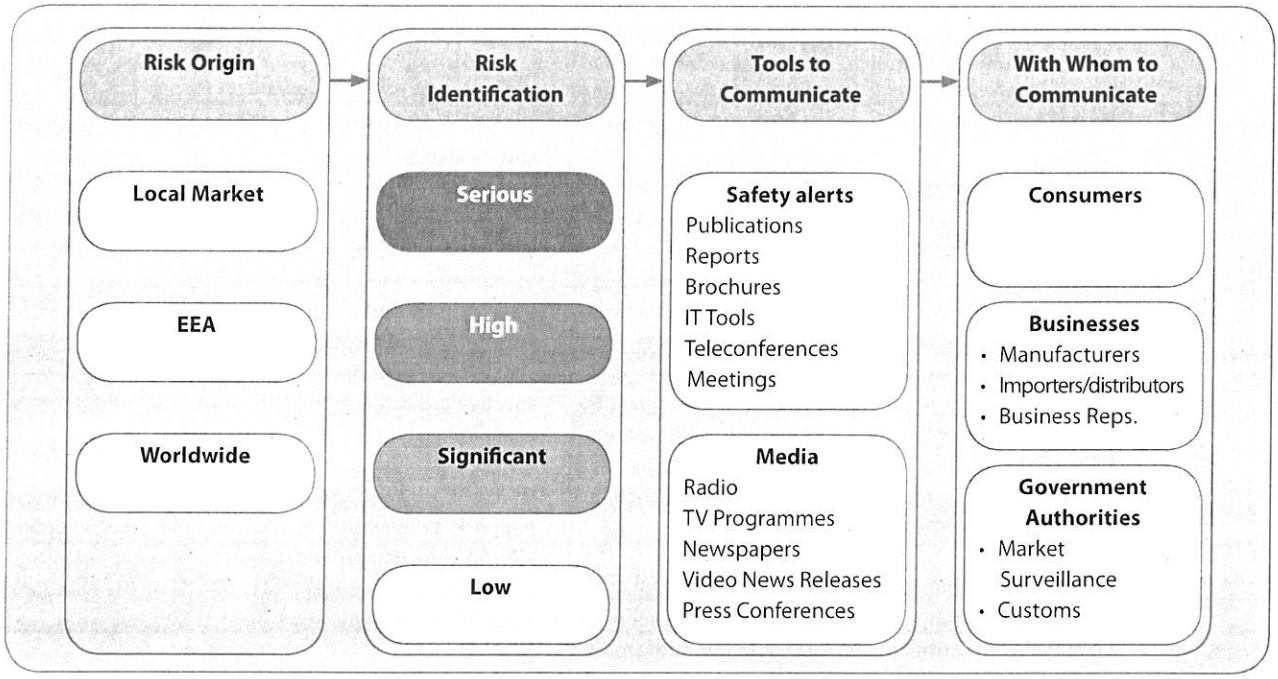


Figure 33: Risk Analysis and Risk Communication Steps.

The European Commission and the Member States are carrying out continuous research in order to improve the existing communication tools and to identify and develop new effective tools that will contribute to both faster and more efficient communication. The Internet is a valuable tool used for communication between Member States. Various IT systems have been created and are being used today. These can either be available to the public on the public domain such as the weekly RAPEX reports published by the European Commission on its website or they may be restricted to public officials within the Member States.

D.2 Communication in the field of product safety

In the field of product safety, communication is being carried out using the following methods:

- Regular meetings between the European Commission and the Member States
- IT Tools
- Media
- Reports
- Teleconferences
- Brochures

The use of the above mentioned methods of communication depends on the objectives of communication. For example, in case of a dangerous product posing a risk to the health and safety of consumers in a particular Member State, a rapid communication channel between all Member States is essential, so that they can take the necessary action to eliminate the risk or reduce it to an acceptable level.

The tools that are currently used for dissemination of information are the following:

- RAPEX
- Safeguard Clause Notification Procedure
- ICSMS
- CIRCA
- European Commission Website

Apart from the ICSMS system, all other systems are used by all the Member States and have their own objective and scope of application. Detailed descriptions of these systems can be found in Annex H.

D.3 How to inform consumers and media of dangerous products and instructions on how to react in order to avoid dangerous situations

If we work together in order to create the best market surveillance institutions with the best market surveillance officers having a brilliant and foolproof proactive market surveillance system, unsafe or non-conforming products would still be supplied to consumers. One has to keep in mind the considerable amount of products that are found on the European market and also the new importers who are not aware of the European legislation. This is the reason why the Market Surveillance organisations shall always have an effective readily available method so as to communicate with the people at risk when they encounter hazardous products. This may serve as a contingency plan.

Figure 34 on in the following page shows the strategy and methodology of a risk communication procedure. Reaching the target audience in the shortest possible time with clear objectives and instructions can save lives.

The first thing to tackle is to determine the importance of the information campaign, and whether this has to be carried out in order to recall a very hazardous product from the consumers or whether it is simply to obtain some information from the general public or a segment thereof.

Hence prior the communication strategy, there should be a clear objective why communication is necessary and clear goals have to be identified. The next step is to identify the kind of environment that the information will be introduced into and the target audience. In the field of product safety, the target audience of the market surveillance organisations can be either the Business sector (manufacturers/importers) or the consumers. The 'consumers' group can be subdivided into further segments (age group, class, lifestyle, gender or education) as shown in Figure 34.

Following the identification of the target audience, one must determine the most feasible and viable tool to communicate (please refer to Figure 32 Risk Analysis). Nowadays, there are various tools that offer effective and rapid communication throughout the entire spectrum and this depends on the particular situation and the target audience.

Prior to the communication step, it is important to identify any potential obstacles that may hinder the effectiveness of the communication. One must try to minimise these obstacles as much as possible. If there are doubts on the effectiveness of the method, the communication method may also be revised accordingly.

At this stage, the person communicating the risks with the target audience shall start anticipating any questions or possible reactions from the target audience and prepare the response beforehand. It is quite important to have technical officers that give complete, clear and reliable instructions when answering any questions from the target audience.

When all steps mentioned above have been tackled, communication has to take place. The effectiveness of the communication strategy can be assessed by various methods, for example, checking the feedback obtained from the target audience, the use of questionnaires / surveys or other methods.

The media is an important tool to be used when a dangerous product is distributed within the market. Before making the statements to the media, public officials have to be extremely careful. In order to effectively communicate, one has to establish clear communication goals and key messages. Once goals and messages have been established, the challenge becomes one of delivery and ensuring that messages are heard and goals are met.

The public should only be informed when one of the products encountered on the market poses a risk to the health of the consumer. The competent national authorities should take the immediate necessary actions to withdraw the product from the market and to order the distributor to recall the product from consumers. When the voluntary action is not immediately taken by the distributor/responsible person, the national authority should be responsible for withdrawing the product from the market and to issue the public statements in order to protect the health of the consumers.

When informing the general public the authority must consider that individuals, e.g. users of the product, might have further questions on the information given. Therefore, it is important to provide a contact person (or some other source) where such information can be obtained. One must also consider whether the number of reporting consumers will be higher than what one person can handle. It will rarely be the case provided that the information that is published is clear and sufficient.

Furthermore, the media will often want to follow up the case – especially when the hazard associated with the product is serious and obvious, if serious accidents have occurred, or if the product is widely in use. In such cases the contact person must be trained in contacts with the media or instructed how to handle a call from a journalist.

When communicating through the media the following have to be in place:

- Clear communication goals and key messages
- Information delivered with brevity, clarity, and effectiveness
- Accurate information

When issuing a press release, the officer should ensure that it has the following information:

- Contact details of the authority issuing the press release
- Contact person – head of unit
- Picture of the product
- Description of the product
- Model number and batch number
- The danger posed with the product without in-depth technicalities
- What to do with the product
- The contact details of the distributor or manufacturer

The individual or office sending a risk message or interacting with other individuals, groups or organisations in a risk communication process, may also be the risk manager, risk message preparer, risk analyst or other expert.

It is considered to be best practice that market surveillance officers working with the media get appropriate training. Courses are available through numerous commercial providers.

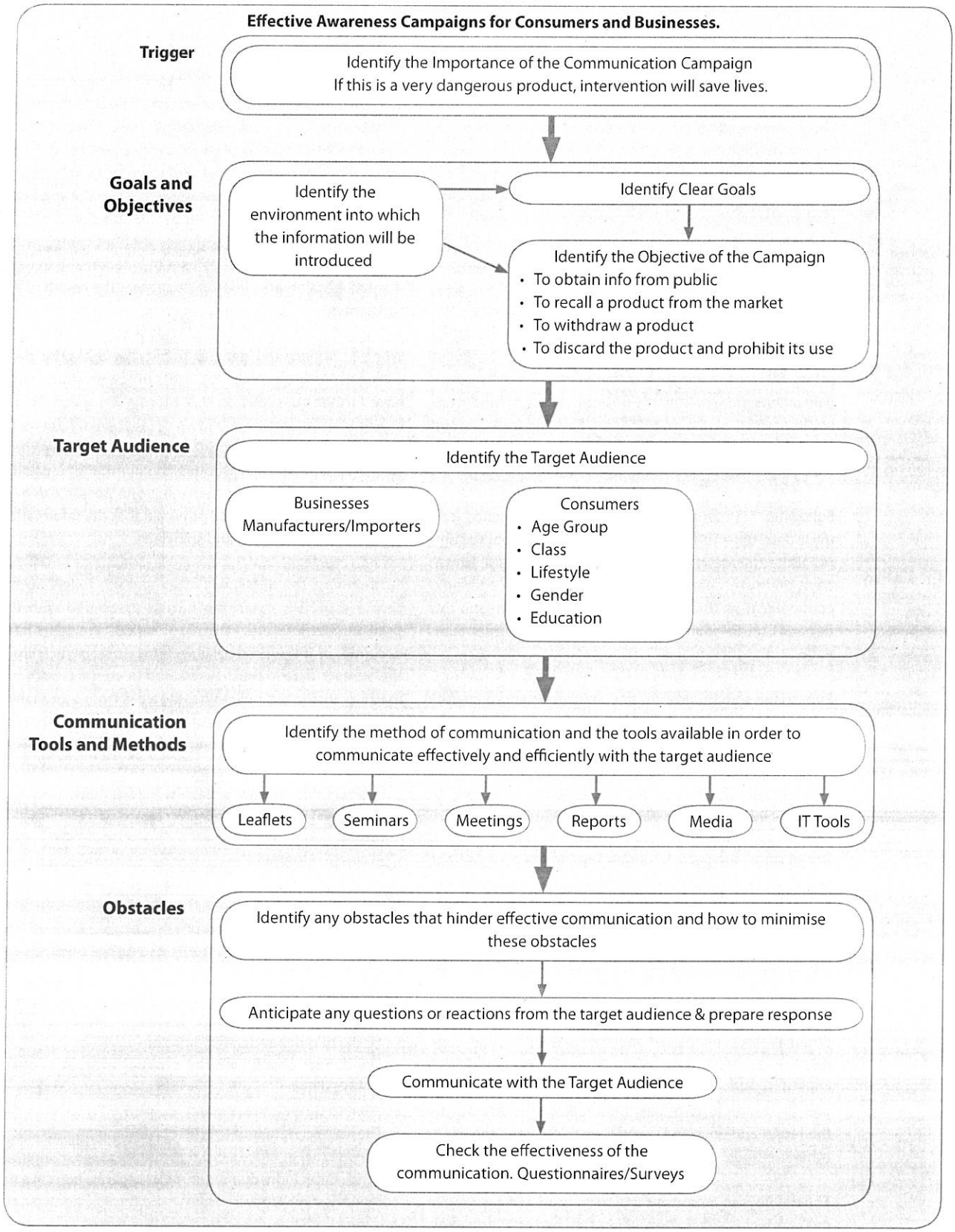


Figure 34: Effective awareness campaigns for consumers and businesses.

D.4 Additional practical ways of exchanging information on risk / product know-how

D.4.1 ADCO GROUPS

There are various Administrative Co-operation Groups (ADCO Groups) for the market surveillance of non-food products. These groups normally meet around twice a year and are normally composed of representatives of Member States' market surveillance authorities and were established to pursue the following objectives:

- to exchange information between Member States' authorities concerning the national market surveillance mechanisms and the adopted solutions;
- to achieve of a uniformly high level of enforcement of the relevant EU legislation;
- to reduce the overlapping of national surveillance operations;
- to diffuse good market surveillance practices; and
- to exchange views and solve practical problems.

These groups are chaired by different countries depending on who is elected for the position. In-house groups elections are conducted periodically in order to determine who will chair the meetings. The meetings are hosted in different Member States. The following are the existing ADCO groups according to the different directives;

- ATEX – Equipment to be used in explosive atmospheres
- Construction Products Directive
- Electromagnetic Compatibility Directive
- Toy Safety Directive
- Gas Appliances Directive
- Lifts Safety Directive
- Low Voltage Directive
- Machinery Directive
- Noise Emissions Directive
- Personal Protective Equipment Directive
- Pressurised Equipment Directive
- R&TTE (Radio & Telecommunications Terminal Equipment Directive)
- Recreational Craft Directive
- Medical Devices Expert Group

Those directives that do not yet have the ADCO group might have one in the future.

D.4.2 GPSD Committee and Network

The GPSD (GPSD) Committee is composed of the representatives of the Member States to the Committee created under Article 15 of the Directive 2001/95/EC of 3 December 2001 on general product safety. The objective of the Committee is to assist the Commission in the implementation and practical application of the Directive.
The GPSD Network is composed of the contact authorities in the Member States for the Network created under Article 10 of the Directive. The objective of the Network is to facilitate improved collaboration at operational level on market surveillance and other enforcement activities, in particular risk assessment, testing of products, exchange of expertise and scientific knowledge, execution of joint surveillance projects and tracing, withdrawing or recalling dangerous products.

D.4.3 PROSAFE – EMARS PROJECT

PROSAFE (the Product Safety Enforcement Forum of Europe) is an organisation established entirely by enforcement officers throughout Europe who deal with the safety of consumer products. The first formal meeting of the group was in 1990. Since that time, most EU Member States and EFTA (the European Free Trade Association) countries have been represented at meetings. The background of PROSAFE was a common recognition of the need to build links in operational understanding and trust between enforcement officials charged with the task of working together to enforce community law.

PROSAFE coordinates the project EMARS, 'Enhancing market surveillance through best practice' with financial support of the European Commission. The project aims to ensure a basic level of expertise and practical experience in most of the market surveillance organisations of Member States within the EEA.

This project has established a couple of tools for exchanging information between market surveillance officials. Further details on these systems can be found in H.2.4.

ANNEX E – THEORY ON TARGETING OF MARKET SURVEILLANCE

In this Annex the results of studies performed by the Law Enforcement Expertise Centre of the Dutch Ministry of Justice ('Table of Eleven'[1]) on the targeting of market surveillance are presented for reference.

The target group for the Table of Eleven included policy makers, jurists drafting legislation and enforcers for whom much of what is discussed is directly beneficial in helping them do their job.

1 Law Enforcement: Expertise Centre of the Dutch Ministry of Justice: The 'Table of Eleven' A versatile tool, November 2004: http://www.justitie.nl/images/English%20version%20versatile%20tool%20oct2006_tcm34-9098.pdf

The Table of Eleven distinguishes eleven dimensions which determine compliance with legislation. These are divided into two groups: spontaneous compliance dimensions and dimensions related to enforcement. Obviously, the latter are of direct interest to enforcement organisations. Nonetheless, awareness of the spontaneous dimensions is useful especially for market surveillance authorities focusing also on compliance assistance.

An overview of the compliance dimensions is presented in Table 14 where the enforcement dimensions have been subdivided in two categories: sanction dimensions and control dimensions. For the purpose of this discussion it shows clearly that the possibilities to influence behaviour are associated with market surveillance.

Table 14: overview of compliance dimensions.

Spontaneous compliance	Enforcement	
	Sanction dimensions	Control dimensions
Knowledge of the rules	Sanction Probability	Inspection Probability
Cost/Benefit	Sanction Severity	Detection Probability
Level of Acceptance	Quality of the rules	Selectivity
Loyalty of the target Group		Risk of being reported
Informal Control		
No or minimal influence	*Indirect influence*	*Direct influence*

E.1 Spontaneous compliance dimensions

1. Knowledge of the rules

When the target group for which the legislations are intended is unfamiliar with the rules, compliance or violation of the rules becomes more or less accidental. Being unaware of the rules, or when the rules are not well understood, violators may unknowingly break the rules, and those who comply may not even know that they are complying. Clearly an effort to disseminate information about the legislation to the affected group and 'compliance assistance' is indicated in this situation.

Besides familiarity with the legislation a second determinant is the clarity and/or complexity of the legislation. Complex legislation may require technical or legal knowledge which may not be present in (all of) the target group. This certainly holds true for parts of the product safety legislation (e.g. LVD, Machines, GPSD and most other directives which refer to standards) where it is not uncommon that the businesses involved lack the expertise to interpret the technical requirements. Here also straightforward law enforcement may well be less effective than compliance assistance.

2. Cost/Benefits

Compliance with legislation may induce costs but also benefits to the economic operator. The same applies for non compliance which may result in (short-term) financial and economical benefits, but carries the risk of financial penalties and other disadvantages.

Included in this dimension are intangible costs and benefits, like for example the image that a business wants to maintain, but not the costs and benefits due to inspections and sanctioning from the market surveillance authorities. These are discussed separately in the section on enforcement dimensions.

For economic operators in the field of consumer product falling under the New Approach Directives, obvious costs of compliance are those involved in maintaining the files and declarations of conformity and the costs involved in assessing conformity with the standard. Conversely disregarding the rules saves these costs at the risk of being caught and a deteriorating reputation. Having excluded the influence of law enforcement in the scope of this dimension, the significance of this dimension is mainly for legislators and policy makers, who can influence the balance between costs and benefits by designing legislation that takes this dimension into account. Possibilities include subsidies and levies, certification schemes etc.

Note, however, that the balance between costs and benefits may vary between economic operators; companies depending on their reputation (often big companies) are more inclined to spend in order to comply than those operators and traders that engage in short-term trade and frequently change identity. In the approach of such target groups such differences should be taken into account.

3. Extent of acceptance of policy objectives and of the effects of the policy, and the target group's respect for authority

Acceptance is related to the subjective view of the target group with respect to the reasonableness of the legislation and its consequences for the target group. Unwillingness to accept a rule is seen for example in young adults from certain regions who are obliged to wear helmets on mopeds under traffic laws. The degree of respect for authority is particularly difficult to influence. Acceptance can be raised by involving the target group and other stakeholders in developing the policies and making the target group itself partly responsible for the success of the policy by self-regulation.

These two dimensions are hardly relevant to market surveillance authorities in the field of consumer product safety. Because industry has been and is deeply involved in the development of regulations, both in the phase of developing the New Approach Directives and in the process of standard development, industry is in a sense committed to these rules. Moreover, market surveillance authorities have few means to influence these dimensions of target group behaviour.

4. Non-official (or social) control

Social control is the influence of the community, like friends, colleagues, auditors and other companies and competitors. The impact of social control is dependent on the perceived risk of detection, the degree of (dis)approval of the violating behaviour and the extent to which the community takes action (social sanctions).

Non-official control is the form of formal control that is accepted in certain groups and industries to raise their professional standards by codes of conduct, certification schemes and the adoption quality marks.

E.2 Enforcement Dimensions

The Table of Eleven distinguishes six dimensions that directly influence the impact of enforcement activities on the target group. Two of these dimensions are generally not under the direct control of the market surveillance authorities. The remaining three are directly influenced by the choices market surveillance authorities make with regard to their activities.

For the purpose of this discussion we will divide the enforcement dimension therefore into two groups: the sanction dimensions and the control dimensions.

E.2.1 Sanction dimensions

1. Risk of sanction

The perceived risk of sanction is that an inspection and the detection of a violation will actually be followed by a sanction. Lack of manpower in the juridical system and policies for dismissing charges are common reasons why violations in some cases do not result in punishment. Compliance is not encouraged when the target group is aware that the chance of sanction after detection of a violation is small.

2. Severity of sanction

The severity of the sanction and additional disadvantages of being sanctioned (loss of reputation, legal costs etc.) influence compliance behaviour. This parameter does not have the same impact on all offenders or target groups, however, and the speed and certainty of sanctioning may also influence the impact (tit-for-tat approach) (see 'risk of sanction').

Though increasing the risk of sanction and the severity of the sanction encourage compliance behaviour, they are largely outside the control of the market surveillance authority. The severity of sanctions is generally determined by legislation and the probability that violations are punished depends on the priorities of and capacities in the prosecution and court systems.

In some Member States the probability of sanctions has been raised by allowing the market surveillance authority to impose certain sanctions itself, bypassing the complicated legal procedures required by penal law. Depending on the jurisdiction this competence may for example be founded on administrative law which still provides appeal possibilities for the accused. Because administrative sanctions can be imposed quickly, such measures also raise the effectiveness of sanctions (tit-for-tat).

E.2.2 Control dimensions

1. Perceived risk of being reported

This dimension is concerned with the perception of the offender that violations are disclosed without the intervention of the authorities themselves – for example, tipping by competitors and the general public. In non-food product safety a good example is consumer complaints to the authority. Raising the perceived risk of being reported is clearly within the scope of the market surveillance authority. This can be done by running a well-organised and easily accessible consumer complaints system and widely advertising its accessibility (see 3.7.2).

2. Risk of inspection

Compliance behaviour is stimulated when the risk of being inspected is perceived as being high. The perceived risk of being inspected is of course largely under the control of the market surveillance authority which can determine the frequency of inspections in the target group. The effect on behaviour can be increased when the ac-

tivities to be undertaken are widely communicated in the target group, as this raises the perceived risk of being inspected (enforcement communication).

3. Risk of detection, either from inspection of the records or from physical inspection
Apart from the probability of being inspected it is useful to increase the probability of detection of violations during inspections. Inspections that do not uncover the violations of offenders do not impress the offenders. Therefore, it is important to think about the required 'depth' of the inspections and lab tests for a target group, in order to raise the detection rate of violations and, again, to communicate the high risk of detection.

4. Selectivity
Selectivity concerns the ability of the authority to inspect selectively those violating the rules, while leaving those that comply at ease. Improved selectivity increases the risk of offenders to be discovered.

Note that improving selectivity means concentrating on businesses that are more likely to be offenders and is therefore in line with the initiatives in some Member States (and also the EU) to reduce the administrative burden on industry. To raise selectivity, an analysis of the target groups is necessary. Data from previous inspections, generally available in market surveillance organisations, is useful information for this purpose.

E.3 Analysis of compliance in target groups

The dimensions described cover the main factors that determine compliance behaviour. These dimensions are relevant for a wide range of legislation, not only non-food product safety legislation. Indeed, they address not only market surveillance, but the many other underlying factors that stimulate or discourage compliance as well. As such, they are relevant for the legislator which can take these factors into account when designing legislation, for example by paying attention to the clarity of the regulations. Also, analysis of the target group against these dimensions may point to specific policies suited to encourage compliance. Such policies might include amongst others organisation of certification schemes, subsidies designed to encourage desired behaviour and to educate the target groups.

Until recently, most market surveillance authorities restricted their activities to enforcement of the legislation by performing inspections and intervening where non-compliances were found. Lately, however, several market surveillance authorities have embraced additional intervention methods which in specific circumstances are believed to be more effective in raising compliance levels than pure enforcement. Especially assisting businesses in compliant behaviour by providing the necessary information about the legal requirements (compliance assistance) is applied. Compliance assistance is useful for those operators that are unaware of the requirements, but willing to comply.

It is important to note that in the surveillance dimensions it is the perceived risk of being inspected or detected, not the actual risk that influences compliance behaviour. The perceived risks of detection and inspection can be influenced, for example by communicating planned surveillance action in advance. Informing the target businesses of enforcement actions aimed at them attempts raises the perceived risk of inspection which itself encourages compliant behaviour, because it shifts the cost/benefit balance.

Compliance behaviour is determined by a few core dimensions, rather than by the correlation of all dimensions, e.g. 80% of compliance behaviour is determined by 20% of the dimensions (see ref. 4). These core dimensions vary with the legal requirements and also with the target group. Identifying the core factors that determine the compliance behaviour in target groups allows tailoring a specific approach to raise compliance levels of the target group to specific legislation.

To perform this analysis the target group is scored on all the dimensions which for this purpose are grouped according to whether they encourage or discourage compliance. For example, increase of the enforcement pressure (the enforcement dimensions) encourages compliance, while unfamiliarity with the rules can be seen as encouraging violations. The other dimensions can both encourage or discourage compliance. Plotting the score against the dimensions then gives a compliance profile as shown in Figure 35.

Figure 35 is an example that shows an analysis performed on a target group consisting of operators/proprietors of amusement rides. The rides must be subjected to a safety test by a certification institute which checks if they comply with the safety requirements. If shortcomings are detected, these must be corrected, sometimes requiring substantial investments. The figure shows at a glance the strong and weak reasons for compliance in the target group and thus indicates which dimensions need attention in order to promote compliance. Note that some dimensions have been subdivided in more specific varieties.

Though the results of this analysis must be interpreted with care, it gives a useful indication of the possibilities for enforcement to improve compliance levels, or alternatively that other approaches are more likely to succeed. It is important to consider that behaviour is not determined by the actual factors themselves, but by the way those factors are perceived by the target group.

For meaningful scoring of the dimension for the target group knowledge of the target group is of course a necessity. The information required may partly be available from previous experiences of the market surveillance authority, but can also be obtained by questioning the target group. Since the latter may be expensive, questioning experts what they believe to be the reasons for a particular type of behaviour is sometimes used. A computer programme to facilitate the process for a group of experts is available: http://www.it11.nl/it11/login.jsp. Access can be obtained via the site by requesting a login code.

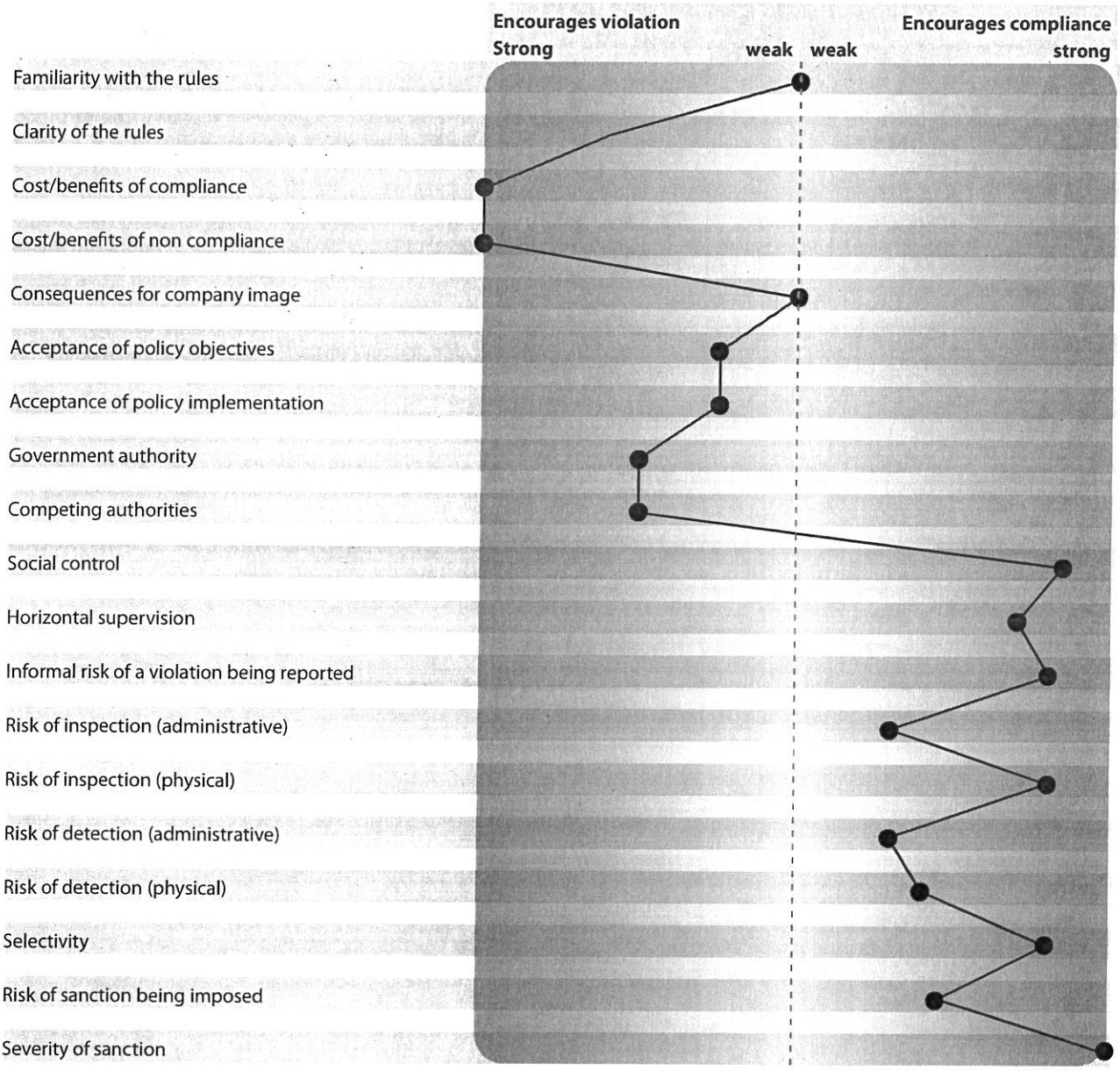


Figure 35: Compliance profile for operators/proprietors of amusement rides.

E.4 Characterisation of the target group

The target group is not homogenous; there will be economic operators that comply with the rules and operators that violate the rules. For both groups the reasons they behave the way they do may differ. The effectiveness of the interventions by market surveillance authorities is dependent on the reasons for compliance behaviour. Distinguishing sub-groups within the target group, on the basis of the reasons for their compliance behaviour, can then contribute to an approach tailored to give optimal effects.

The target group can for instance be distinguished into the following groups:

- *Unconsciously compliant people:* this group is unfamiliar with the rules, but unknowingly complies with them (more or less by chance);
- *Unconsciously non-compliant people:* this group breaks the rules unconsciously because they are not familiar with the rules;
- *Spontaneously compliant people:* those who know the rules and spontaneously comply. For this group no enforcement is needed;
- *Spontaneously non-compliant people:* those who know the rules but spontaneously break them, regardless of the risk of sanctions or punishment;
- *Calculatingly compliant people:* those people that know the rules and would break them, but who are deterred by the risk of inspections and sanctions;
- *Consciously or calculatingly non-compliant people:* those people that knowingly break the rules and consciously accept the risk of being caught.

Finally, there is a group that can not be or is very hard to influence. This group is either respectful to authority (and therefore complies) or disrespectful to authority, in which case they are likely not to comply.

The original purpose of this attempt to characterise the target group for a specific kind of legislation was to estimate compliance levels to be expected for this legislation. Proper characterisation requires insight into the target group. To facilitate obtaining that insight a complicated technique involving the answering of a large number of questions by experts, facilitated by software, was developed: http://www.it11.nl/it11/login.jsp. Eventually, the result can be a graph like Figure 36: Compliance estimates for operators/proprietors of amusement rides which shows the composition of the target group at a glance.

For market surveillance authorities collecting information that gives a reliable idea of the composition of the target group allows drawing up a more or less reliable image of the target group. This in turn helps in determining the proper intervention methods and to direct enforcement activities to those operators that are most likely to violate the legislation. For example, education of the unconsciously compliant group may initially be the preferred approach. The same kind of intervention may also help to improve the compliance behaviour of ignorant offenders that might well be willing to comply once they are aware of the rules.

Contrarily, enforcement by inspecting and testing is more likely to work for deliberate offenders and is required to keep the conscious economic operators complying.

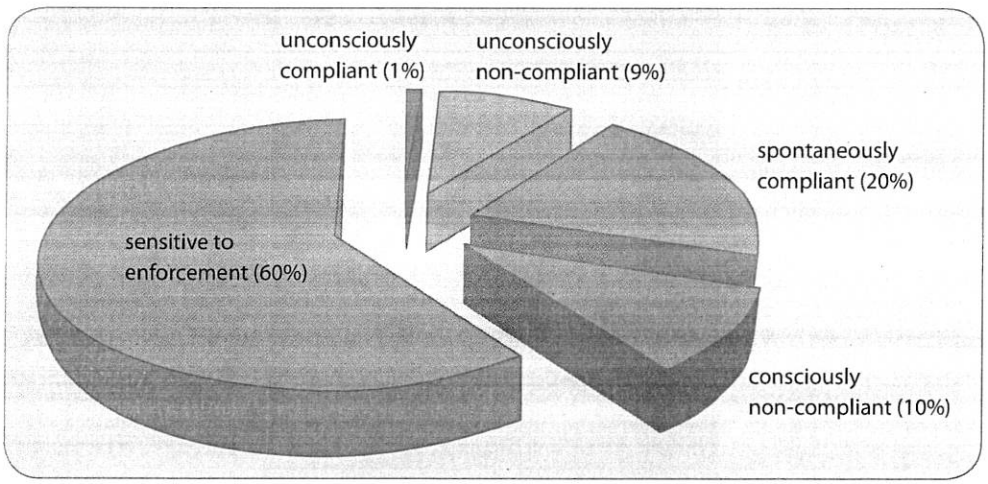


Figure 36: Compliance estimate for operators/proprietors of amusement rides.

ANNEX F – FAILURE CODE LIST

	Remark 1	Criticism 2	Serious criticism 3
Technical faults			
Accessible live part in normal use			3
Accessible basic insulated parts on class II products		2	
Luminaries and domestic equipment of class 0	1		
The creepage and clearance distance is less than 10% of the requirement in relevant standard			3
The creepage and clearance distance is more than 10% and less than 50% of the requirement in relevant standard		2	
The creepage and clearance distance is more than 50% of the requirement in relevant standard	1		
Cord extension set with class 0 plug and class 1 outlet	1		
Cord extension set with class 1 plug and class 0 outlet			3
Cord extension set with class 2 plug and class 0 or 1 outlet			3
Class 1 plug mounted on a supply cord without protective earth conductor, changing a class 1 appliance into a class 0 device			3
Phase and earth exchanged by mistake in earthed coupling			3
The equipment lacks thermal cut-outs and/or current cut-outs		2	(3)
The rated current in the equipment is one step too high	1		
The rated current in the equipment is more than one step too high		2	
The rated current in the equipment is so high that it is a fire hazard			3
Marking is incomplete or missing		2	(3)
CE-mark is missing	1	(2)	
Incomplete and wrongful instructions for use and/or mounting which can cause danger		(2)	3
National language operation instructions with necessary safety information are missing		2	
The design diverges from standard or technical documentation		2	(3)
Conductors not adequately attached		2	(3)
Risk of mechanical damage to conductor		2	(3)
Equipment with inadequate conductor (cross-section, insulation)		2	(3)
Cord anchorage is missing		2	(3)
Ip classification does not comply with the requirements		2	(3)
The design diverges from standard or technical documentation (great risk for electrical shock/fire)		2	(3)
Administrative procedures			
Declaration of conformity is missing		2	
Errors in declaration of conformity	1		
Technical documentation is missing		2	
Errors in technical documentation	1	(2)	
Modified product sold with the same type no. etc. as product where sales ban is issued	1		

(a parenthesis indicates that the code could be used in some cases)

ANNEX G – THE MAIN EUROPEAN / INTERNATIONAL STAKEHOLDERS WITHIN MARKET SURVEILLANCE

Besides national legislators, national policy makers, producers, distributors and individual consumers who complain about specific products, stakeholders' organisations can have a very important influence on the market surveillance policy in several ways.

In this Annex the main international and European stakeholders' organisations in the area of consumer product safety market surveillance are addressed. Follow the respective stakeholder's hyperlink to get more detailed information from their Website.

G.1 International / European Agreements and Treaties

International agreements on world trade (and especially the technical barriers to trade) and the European Treaties have a major impact on the national legislation and policies in the area of consumer product safety. The World Trade Organisation (WTO) and the European Commission act as 'guardians' of the agreements and treaties and both organisations promote the developments and elaboration of the substance of the agreements and treaties.

G.1.1 WTO (World Trade Organisation)

The hyperlink to the website of the WTO is: www.wto.org. Of special interest is the 'Agreement on Technical Barriers to Trade (TBT)' (see article 2.4): this agreement is available on: http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf.

G.1.2 European Commission

The hyperlink to the website of the European Commission is: http://ec.europa.eu. The hyperlinks to the most important Directorate Generals in the area of consumer product safety market surveillance are:

- DG SANCO's (http://ec.europa.eu/consumers/index_en.htm) mission is to help make Europe's citizens healthier, safer and more confident. Part of this task is to keep up to date European laws dealing with the safety of food and other products, on consumers' rights and on the protection of people's health. It is national, regional or even local governments in EU countries who actually apply the EU's health and consumer protection laws. It is their job to make sure traders, manufacturers and food producers in their country observe the rules. DG SANCO checks that this is really happening and that the rules are being applied properly in all EU countries. Moreover, it supports the Member States with these important tasks.
- DG ENTERPRISE (http://ec.europa.eu/enterprise/site-map.htm) has the role to ensure that businesses can compete openly and fairly. The aim is to make Europe an attractive place to invest and work in. Current priorities for Enterprise policy include: promoting entrepreneurship, contributing to the design, implementation and improvement of a flexible regulatory framework providing access to the single market, opening-up of and guaranteeing obstacle-free, fair access to the markets of non-EU countries, promoting European competitive performance.
- DG TAXUD: (http://ec.europa.eu/taxation_customs/taxation/index_en.htm) has the role to monitor the implementation of the EU Tax Policy Strategy and to ensure that tax policy supports broader EU policy objectives.

G.1.3 International and European technical standardisation

International and European technical standards provide the main reference sources for checking the conformity of consumer products. The International and European organisations engaged in standardisation are:

- ISO (International Organisation for Standardisation): http://www.iso.org/
- IEC (International Electrotechnical Commission): http://www.iec.ch/
- ITU (International Telecommunication Union): http://www.itu.int/
- CEN (Comité Européen de Normalisation): http://www.cen.eu/
- CENELEC (Comité Européen de Normalisation Electrotechnique): http://www.cenelec.org/
- ETSI (European Telecommunications Standards Institute): http://www.etsi.org/

G.2 General International and European Stakeholders Organisations

G.2.1 ICPSC (International Consumer Product Safety Caucus)

The ICPSC was founded in 2004 in order to facilitate the exchange of information on consumer product safety issues with a view to strengthening the collaboration and cooperation among governments and regulatory agencies around the world.

Members of ICPSC include: Asia (NITE, AQSIQ, KATS), Australia (Australian Competition & Consumer Commission), North America (CPSC and Health Canada), Europe (European Commission, DG SANCO and PROSAFE).

G.2.2 ICPHSO (International Consumer Product Health and Safety Organisation)

The International Consumer Product Health and Safety Organisation was founded in 1993. ICPHSO is an organisation dedicated to the health and safety issues related to consumer products manufactured and marketed in the global marketplace. The hyperlink to the website of ICPHSO is: http://www.icphso.org/.

ANNEX G – THE MAIN EUROPEAN / INTERNATIONAL STAKEHOLDERS WITHIN MARKET SURVEILLANCE (Continued)

G.2.3 EuroSafe

EuroSafe, the European Association for Injury Prevention and Safety Promotion, is the network of injury prevention champions dedicated to making Europe a safer place. The hyperlink to the website of EuroSafe is: http://www.eurosafe.eu.com/.

G.3 Business representatives

Most business sectors have specific trade organisations representing their interests. It has also to be noted that similar organisations exist at Member State level.

G.4 Consumer representatives

G.4.1 Consumers International (CI)

Consumer International (CI) is the only independent global campaigning voice for consumers. With over 220 member organisations in 115 countries, CI is building an international consumer movement to help protect and empower consumers everywhere. The hyperlink to the website of Consumer International is: http://www.consumersinternational.org/.

G.4.2 Bureau Européen des Unions de Consommateurs (BEUC)

BEUC's members include 40 reputed, independent national consumer organisations from some thirty European countries (EU, EEA and applicant countries). BEUC acts as a sort of 'embassy' for these organisations in Brussels and our main task is to represent our members and defend the interests of all Europe's consumers. The hyperlink to the website of BEUC is: http://www.beuc.eu.

G.4.3 European Consumer Consultative Group (ECCG)

In EC Decision (2003/709/EC) of 9 October 2003, the European Commission created the European Consumer Consultative Group (ECCG). This body replaced the Consumer Committee as the Commission's main forum for engaging with consumer organisations. The hyperlink to the webpage on the EU website of ECCG is: http://ec.europa.eu/consumers/cons_org/associations/committ/index_en.htm.

G.4.4 ANEC

ANEC (http://www.anec.org) is the European consumer voice in standardisation, representing and defending consumer interests in the process of standardisation and certification, also in policy and legislation related to standardisation.

ANEC was set up in 1995 as an international non-profit association under Belgian law and represents consumer organisations from the European Union Member States and the EFTA countries.

G.5 PROSAFE

PROSAFE is the forum where European Market Surveillance Authorities meet and inform each other of upcoming risks, developments in the Member States in relation to market surveillance, exchange best practices and discuss about the future of market surveillance.

The hyperlink to the website of PROSAFE (the Product Safety Enforcement Forum of Europe) is: http://www.prosafe.org/.

G.6 EMARS

EMARS is a project of PROSAFE, funded by the European Commission. One of the aims is to improve market surveillance in Europe by gathering and developing best practices in market surveillance. Most Member States participate and make contributions.

The hyperlink to the website of EMARS (Enhancement Market Surveillance, a PROSAFE project, partially funded by the European Commission) is: http://www.emars.eu.

G.7 Sectorial Administrative Cooperation Groups (ADCO's)

Further information on the activities of sectorial Administrative Cooperation Groups (ADCO's) can be retrieved from the 'Communication & Information Resource Centre Administrator' (Circa) of European Commission (access only for the members of the sectorial ADCO's): http://circa.europa.eu/Public/irc/enterprise/Home/main.

ANNEX H – CROSS-BORDER INFORMATION SYSTEMS

H.1 Systems based on legal obligations

For effective pan-European market surveillance close co-operation between the market surveillance authorities in the Member States is a necessity. A number of information systems are in place to facilitate this. The use of some of these systems follows from legal obligations laid down in the GPSD or sectorial directives, whereas the use of other systems is voluntary (even though highly recommended).

H.1.1 RAPEX

RAPEX is a European rapid alert system for dangerous non-food consumer products. It is used to disseminate information regarding dangerous products identified in one Member State. In accordance to Articles 11 and 12 of the GPSD, when a Member State takes measures to eliminate risks being posed by a dangerous product, it is obliged to inform the European Commission within a stipulated time frame (please refer to the Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC).

In this regard, the European Commission has established a network of National Contact Points. They are responsible at national level to handle such information, to distribute it to the competent authority responsible for the particular product (depending on the market surveillance structure at national level) and to report back to the Commission the action(s) taken by the competent authority to eliminate the communicated risk (if any).

When a Member State takes a measure to eliminate the health/safety risk posed by a dangerous product, it must immediately inform the Commission. The Commission evaluates whether the data is complete and the notification meets the legal requirements. If the information is pertinent and sufficiently complete, the notification is transmitted to the network of national RAPEX Contact Points. The Contact Points distribute the notification to the relevant national authority responsible for the particular product category for the necessary follow-up. After the national authorities have investigated the issue and, if the product is found, taken the necessary follow-up action to eliminate or minimise the communicated risk, the Contact Point reports back to the Commission and information on the follow-up is communicated back to all the other Member States via RAPEX. The procedure is illustrated in Table 15.

Table 15: The functioning of the RAPEX System

Step 1	RAPEX notification is sent to the European Commission by one Member State
Step 2	Data verification by the European Commission
Step 3	Validated RAPEX notification is sent to all Members of the EEA for the necessary follow-up
Step 4	The Member States that find the product on their national markets, have additional information on the product or the risk or contest an element of the RAPEX notification informs the European Commission as to their reaction.

Information on RAPEX notifications on products posing a serious risk to consumers are published weekly on the Commission's website at http://ec.europa.eu/rapex for the benefit of consumers, economic operators and other stakeholders.

Step 4 in Table 15 requires that Member States take actions to investigate the market for the presence of dangerous products notified in RAPEX. Experience shows that the follow-up to notifications can be a time-consuming and complicated process. Input from Member States also shows that practices vary between the Member States.

These methods can consist of:

- Visiting retailers on a random basis or more extensively can be performed as a short-term action. This method has a great chance of success since large parts of the market will be examined in a relatively short time period. The greatest disadvantage of this method is that it is resource-intensive, especially when larger parts of the market are to be investigated.
- Information on the product on the authority's website that is available to all interested parties, i.e. consumers, media and business. Experience shows that this method is not widely used. Efforts should therefore be made to enhance the use of this information channel. For consumers easy access and good usability are key issues. For businesses and other stakeholders, a subscription system is recommendable.
- Advertising or other actions in media, especially on products posing a very serious risk might create some interest with the consumers and businesses and consequently result in information of the presence of the product in the national market.
- Workshops and seminars intended for manufacturers, importers and possibly retailers increase awareness on the GPSD and the RAPEX system and the obligations this system poses for economic operators. Topics for such events can include risk assessment, RAPEX statistics etc. These events can be used as a means to inform these stakeholders of the presence on a given national market of a dangerous product inviting them to cooperate in monitoring and removing similar situations on other markets.

Link to list of national contact points: http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_weekly/contact_points_revised.pdf.

Link to weekly published reports of dangerous products: http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm.

H.1.2 Safeguard Clause Procedures

All the New Approach Directives include a 'safeguard procedure'. In many of the Directives this procedure is described in Article 7. In the Low Voltage Directive the procedure is under Article 9 and it is also slightly different from the template of the safeguard procedures in the other directives. The reason for this is that the LVD was originally conceived and adopted before the New Approach.

The safeguard procedure is not meant as an information exchange tool. The main aim of this procedure is to safeguard the free circulation of goods by providing the Commission with a means to analyse the justification of national measures restricting the free circulation of goods. The safeguard procedure may also play a role in the information exchange between the authorities on dangerous and non compliant products, and in the area of the LVD it indeed does so.

The safeguard clause procedure obliges Member States to take CE marked products that endanger the safety or health of their citizens (and sometimes also when they endanger domestic animals or property) from the market and to inform the Commission that they have done so.

Safeguard clauses must be invoked by the Member State for products falling under a New Approach directive that present a substantial hazard, even if the products are correctly constructed, installed and maintained and used according to their intended purpose. For this product the Member State must have taken national measures which restrict or forbid the placing on the market of the product, or have the product withdrawn from the market. Furthermore, these measures should have binding legal effects.[1]

Member States are required to inform the Commission of the reason for their decision, in particular whether non-conformity is due to:

- failure to satisfy the essential requirements;
- incorrect application of the standards;
- shortcomings in the standards themselves.

After investigation, the Commission informs the Member State about the conclusion reached, either that the measure was justified, or that it was not. When the Commission judges the measure justified the case is settled. If the Commission decides that the measure was not justified, the authority has to decide whether it wants to comply with the ruling of the Commission or not. When it does, it has to take the measure back and allow the continuing trade of the product on its market (and possibly pay compensations for lost profits and other costs).

When it upkeeps the measure despite the Commission opinion, it risks being called before the European Court of Justice, either by the Commission or the manufacturer/importer affected for imposing an illegal barrier to the free circulation of goods.

Besides informing as to the reasons for the measure, there are a few practical matters to consider when submitting a safeguard notification. The notification is a legal obligation of the Member State and should be handled as such. The exact procedure to submit is dependent on the organisation of the Member State, but commonly notifications should be forwarded officially through the Permanent Representations of the Member States. This official procedure must always be followed, in view of the legal significance the process may have. Because in some cases the official way may be a slow process, and may also be error prone, parallel direct delivery to the Commission official in charge of the Directive can help to prevent confusion.

Safeguard clause notifications for products that comply with the relevant European standard, but which do not comply with the essential safety requirements, require special attention. Because those products satisfy the standard requirements they enjoy the assumption of conformity. In all fairness their producers or importers can then hardly be blamed for the non-compliance. Where the product nevertheless is dangerous and does not comply with the safety requirements of the Directive, a safeguard clause notification can be issued which challenges the European standard directly. Of course, if the product presents a real risk measures to stop, its circulation also must be taken.

Safeguard clause notifications against (parts of) European standards require special care. It must be shown that the safety level the European standard concerned does not fulfil the essential safety requirements of the associated Directive. Plausible evidence that such is indeed the case will most likely be based on a risk assessment. The risk assessment should show that products fulfilling the standard requirements carry nevertheless unacceptable risks, and therefore do not comply with the requirements in the Directive. Since the Commission investigates the validity of the notification and checks the evidence on which it is founded, it will hear the stakeholders involved. This would generally include the affected company and the European standard organisation (CEN or CENELEC) which are given opportunity to react. It is therefore of paramount importance that the notification is soundly argued. In these circumstances getting a second opinion on the risks from an independent institute to substantiate the risk analysis is advised.

1 See: Guide to the implementation of directives based on the New Approach [1].

Relevant in this context is also the 'state of the art' in the field concerned. Though often a vague concept, it helps when products that do not share the same risk are sold on the market. These products should then be comparable, making them indicative for the 'state of the art'. Less useful in this argument are upmarket products which are much more expensive.

When after investigation the notifying Member State is put in the right, the Commission will publish this in an opinion and will probably draw back the assumption of conformity for (part of) the standard. Most likely the Commission will also draw up a mandate to the standard organisations to adapt the standard to the essential requirements for those risks not covered sufficiently.

In the area of the LVD good practice requires that, when a company within a Member State is the subject of a safeguard clause by another Member State, the Member States' authority carries out an inspection of that company. The company's comments on the safeguard clause should be heard and it should be investigated if the non-conformities indeed exist. If this is the case, proportional measures should be taken and further trade should be stopped. If the charges in the safeguard clause can not be confirmed and the company's defence against the charges is relevant, the Member State can object to the safeguard clause at the Commission. The Commission then investigates the legality of the original measure that spawned the safeguard procedure.

Further information about the operation of the safeguard clause procedure should be sought through the national representative in the relevant ADCO group.

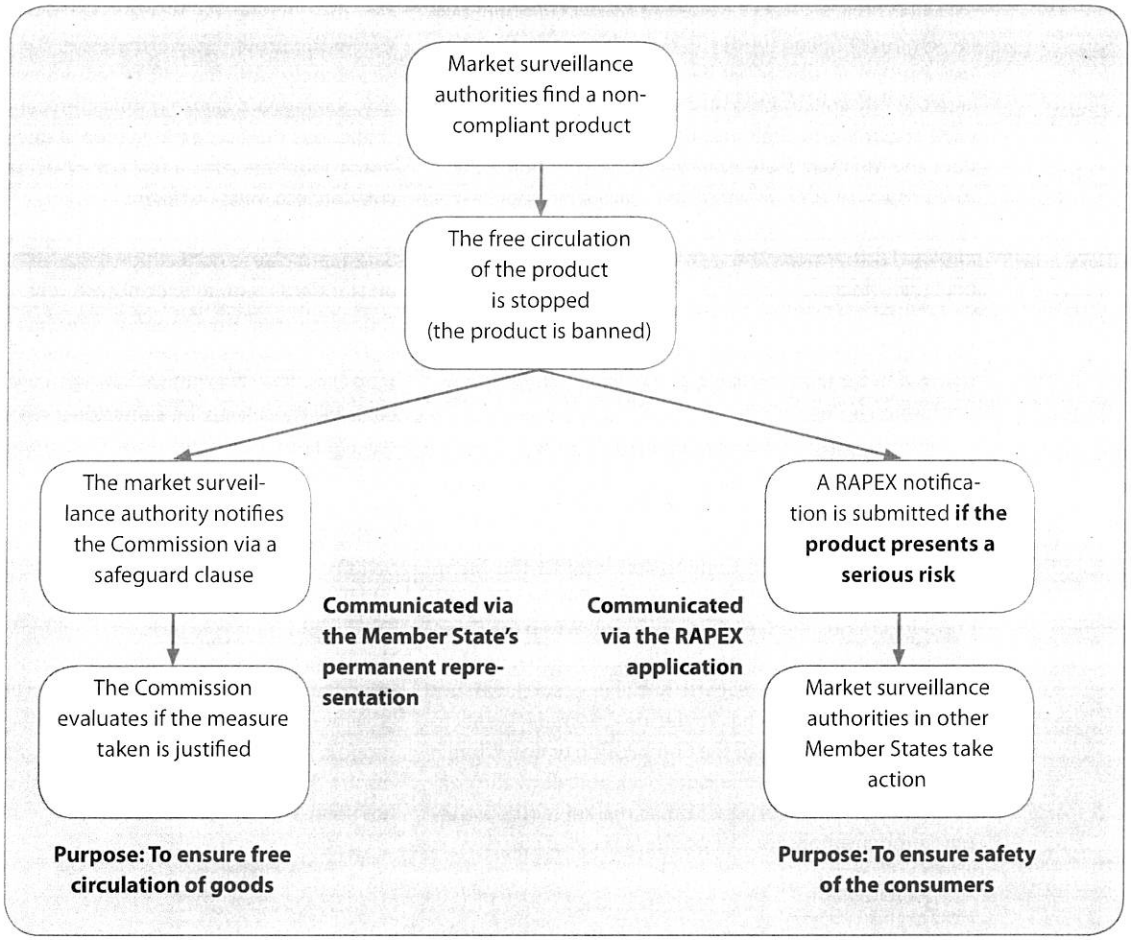


Figure 38: Interaction between the RAPEX procedure and the safeguard clause procedure.

H.2 Voluntary Systems

H.2.1 CIRCA

The Communication and Information Resource Centre Administrator (CIRCA) is a web-based environment, funded and developed, initially for Eurostat, under the European Union IDABC (Interchange of Data Between Administrations) Programme. As the name implies, it is a communication tool. CIRCA allows groups with common interests (working groups, project groups etc.) to share and exchange information and documents and to communicate in a private space on the Internet. CIRCA offers several additional functions.

CIRCA is divided in interest groups that allow public access and interest groups with restricted access. The groups with restricted access can be accessed after a user name and password are obtained. Access and navigation is done via any Internet browser and Internet connection. One member of the interest group plays the role of chairman or moderator; in CIRCA it is called a 'Leader'.

A large variety of interest groups uses CIRCA. These range from groups on specific industries to groups on specific legislation. Participants may be from industry, governments, consumers etc. For market surveillance authorities the restricted access groups set up for the Administrative Cooperation (Ad-Co's), expert groups and the working parties on new approach legislation are important:

- Low Voltage Directive Administrative Cooperation Working Group
- Machinery Administrative Cooperation Group
- LVD WG Update
- LVD Working Party
- Expert Group on Toy Safety
- LVD Notified Bodies Forum
- Machinery Directive

Most of these groups employ CIRCA mainly as a tool to exchange documents and information before their actual meetings. LVD AdCo has employed their CIRCA space also as a means to facilitate the information exchange in the framework of their cross-border actions, allowing the participant's access to the sampling data and test results of the other participants.

H.2.2 European Commission Website

Another very important database can be accessed from the European Commission Website, in the section of the Directorates for Health and Consumers and for Enterprise and Industry. Here, market surveillance authorities, industries, customs authorities and also the consumer can access all the enacted legislation and also the list of standards that are published under each directive.

The information is stored separate for each European Directive and all the recent developments with respect to the legislation itself or the publication of standards can be accessed on the website.

The links to the websites are:
Directorate for Health and Consumers:
http://ec.europa.eu/dgs/health_consumer/index_en.htm
Directorate for Entreprise and Industry:
http://ec.europa.eu/enterprise/index_en.htm.

H.2.3 ICSMS

ICSMS is a system with the main task to provide and exchange product information via the Internet. It is currently being used by eleven Member States; AT, BE, EE, DE, LU, MT, SL, SE, CH, NL and UK. The system is also being considered in the context of some of the joint actions for exchange of information.

ICSMS consists of a closed and a public area. The closed area is for the use of market surveillance bodies, customs authorities and the EU Commission – i.e. official agencies. It contains product information, test results, official measures taken etc. The public area is for the use of consumers and manufacturers. It contains, for example, official information about dangerous products, by manufacturers drawing attention to pirated copies. Here, the consumer can quickly find reliable information about unsafe products. All the information is presented in an easy to understand form; it is kept up-to-date, and can be accessed via an Internet address.

ICSMS enables all users to carry out a specific search. A search can be made, for example, according to individual products, and according to test results for entire product groups. Test results can be obtained for products from specific countries, information can be obtained for products coming under certain directives, safeguard clause notifications, as well as information about manufacturers, importers and dealers. Confidentiality aspects are protected by a complex system of access authorisations. Of course the system and the data contained in it are protected against unauthorised access.

In the EMARS project a survey was carried out to explore the use of the system in the Member States. The survey comprises 21 authorities in eight Member States. The conclusion was that the use of the system varies a lot between the responding organisations. One organisation responded that they had never used the system. Two organisations indicated that they mainly or only use the system to search for information on dangerous products. Five participants indicated that they file information on all investigated products on ICSMS. One more participant indicated that they expect to do so in the near future. Eleven organisations file information on all products with dangerous shortcomings. Three organisations have answered that they have uploaded a few cases to ICSMS for test purposes.

Even though some of the participants have indicated that they only file information sparsely in the system, almost all participants use it as a source of information. Eighteen of the 21 authorities search the database to gather information to be used in their investigations. Two of the eighteen only search ICSMS when planning a project whereas the remaining eight organisations also search ICSMS when products are investigated as part of a campaign, or because of complaints accidents.

Link to ICSMS: http://www.icsms.org/icsms/App/index.jsp.

H.2.4 Information systems under EMARS

The EMARS project has established a couple of tools to enhance the exchange of information between market surveillance officials:

- Knowledge Base

One deliverable of the EMARS project is a Knowledge Base; i.e. a body of knowledge on market surveillance. It is available for market surveillance officials (and the European Commission) via the Internet and is organised within a storage system with good retrieval functions. Furthermore, the Knowledge Base presents links to information about market surveillance on the Internet.

Information about the Knowledge Base and how to access the documents can be found on: http://www.emars.eu/Knowledge_Base.php.

- Rapid Advice Forum

The Rapid Advice Forum is a procedure whereby market surveillance officers can ask questions and get informal advice on market surveillance issues from colleagues throughout Europe.

The aim is to help market surveillance officials reach a correct and non-biased result in complex and complicated questions that the officials often face. The procedure offers rapid and informal first assessment and feedback from fellow officers (from other Member States). This assessment and feedback is given by individual market surveillance officers and is based on their personal experience and expertise. Answers must never be regarded as a binding opinion of a Member State and the person receiving the assessment is in no way obliged to take this assessment and feedback in consideration.

More information on the Rapid Advice Forum can be found on: http://www.emars.eu/Rapid_Advice_Forum.html.

ANNEX I – BIBLIOGRAPHY

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ANNEX J – STANDARDS APPLICABLE TO QUALITY ASSURANCE

Table 16: Overview of standards related to quality assurance in the ISO 9000 and ISO 17000 series.

ISO 9000:2005	Quality management systems – Fundamentals and vocabulary
ISO 9001:2000	Quality management systems – Requirements
ISO 9004:2000	Quality management systems – Guidelines for performance improvements
ISO/IEC 17000:2004	Conformity assessment – Vocabulary and general principles
ISO/PAS 17002:2004	Conformity assessment – Confidentiality – Principles and requirements
ISO/PAS 17003:2004	Conformity assessment – Complaints and appeals – Principles and requirements
ISO/PAS 17004:2005	Conformity assessement – Disclosure of information – Principles and requirements
ISO/IEC 17011:2004	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection
ISO/IEC 17021:2006	Conformity assessment – Requirements for bodies providing audit and certification of management systems
ISO/IEC 17024:2003	Conformity assessment – General requirements for bodies operating certification of persons
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories

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